UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

P&L IMPORTS LLC

Name of FSVP Importer

LA GALVANINA SPA

Name of Foreign Supplier

BLOOD ORANGE SODA | GLASS BOTTLE | READY-TO-DRINK

Name of Product

AUGUST 14, 2020 / AUGUST 16, 2021

Date of Initial Verification / Reverification

AUGUST 17, 2022

Date of FSVP Plan Expiration

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

Status of Review

NUMBER 03

Version

– Confidential –

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OVERVIEW *of* FSVP PLAN

Title 21 of the Code of Federal Regulations requires that *"... for each food you import; you must develop, maintain, and follow an FSVP [Foreign Supplier Verification Program] that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act. . ."* for each product *(and each foreign supplier of each product)* that our client imports, United Safety Agents (USA) has been engaged to undertake and successfully complete all requisite actions on our client's behalf; to analyze, verify, build and maintain this FSVP plan, that our client will now use to keep in compliance with FSVP regulations.

INSTRUCTIONS

Please review this FSVP plan in its entirety and sign where indicated. 21 C.F.R., §1.510 requires that this FSVP plan be kept on file for a minimum of two years after its use is discontinued. All records must be legible and stored to prevent deterioration or loss. If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly. Off-site storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided on-site within 24 hours of FDA's request for review. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter. **Please contact United Safety Agents immediately to report a change in a foreign supplier's process or status**, in the case of an FDA inspection, or with any questions that you may have by email: info@unitedsafetyagents.com, by fax: +1 (888) 557-2649, or by telephone: +1 (888) 551-7403.

TERMS & DEFINITIONS

FSVP Importer *(Importer)*: The importer, is the U.S. owner or consignee of an article of food that is being offered for import into the United States. **U.S. owner or consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Foreign Supplier *(Supplier)*: The foreign supplier or supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States.

Qualified Individual *(QI)*: Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart.

Verified &/or **Approved**: Verified & approved means only that actions were taken to fulfill regulatory obligations. It does NOT mean that the subject product of this FSVP plan is ready for consumption in its current state.

RULES *of* USE

FOREIGN SUPPLIER VERIFICATION PROCEDURES

21 C.F.R., §1.506 (a), (a)(2), (b), and (c) require that written procedures are established and followed to ensure that food is imported from approved suppliers only and that these procedures provide adequate assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented. 21 C.F.R., §1.506 (d) requires that *"... Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, [an FSVP Importer] must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food [an FSVP Importer] obtain[s] from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505."* As an FSVP Agent or Qualified Individual, USA's FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that is at least equivalent to the FDA's domestic standards. in order to accomplish this goal, documentation of a foreign supplier's processes, procedures and control methods will be required. Understanding that all foods may not share identical hazards - their control*(s)* also not being identical - USA utilizes a variety of foreign supplier verification activities to verify that a food's hazards have been significantly minimized or prevented. USA's determination of appropriate supplier verification activities is based on an evaluation of a specific food, its relevant hazards, and its corresponding foreign supplier. The following activities may be used to satisfy the requirements of 21 C.F.R., §1.506 (a), (a)(2), (b), (c), and (d):

A foreign supplier's Hazard Analysis and Critical Control Point *(HACCP)* plan may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's HACCP plan will be included within this FSVP plan.

An onsite audit of a foreign supplier's facility may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's onsite audit report will be included within this FSVP plan.

Sampling and testing of a food may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's reviewed sampling and testing results will be included within this FSVP plan.

A foreign supplier's relevant food safety record(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's relevant food safety record(s) will be included within this FSVP plan.

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

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Certifying documents for a foreign supplier's Qualified Individual(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the certifying documents for a foreign supplier's Qualified Individual(s) will be included within this FSVP plan.

A food's nutritional label(ing) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the food's nutritional label(ing) will be included within this FSVP plan.

Completion of the FSVP Importer's Supplier Assessment Questionnaire and/or the FSVP Importer's Allergen and Intolerance Questionnaire may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the completed Questionnaire(s) will be included within this FSVP plan.

Documentation that a foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination, and that the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.

Documentation that a foreign supplier meets the definition of a qualified facility *(as defined by §117.3 or §507.3)* may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.

The FSVP Importer may rely upon performance of activities by other entities. If the FSVP Importer relies upon supplier verification activities conducted by another entity, the FSVP Importer will review and assess the results of these activities. Notation and documentation of the FSVP Importer's review and assessment will be recorded in this FSVP plan, including documenting that the determination of appropriate verification activities was made by a Qualified Individual.

When the FSVP Importer determines that a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the FSVP Importer will require a copy of the foreign supplier's annual on-site audit results. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's annual on-site audit results will be included within this FSVP plan. After initial verification, the FSVP Importer will require that the foreign supplier provide copies of their annual on-site results at least annually thereafter.

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.

It may be required that the FSVP Importer conduct or obtain documentation of other (not previously mentioned) appropriate supplier verification activity(s) based on the foreign supplier's performance and the risk associated with the food. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the supplier verification activity(s) will be included within this FSVP plan.

FREQUENCY *of* VERIFICATION PROCEDURES

All above noted foreign supplier verification procedures and activities will be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Please refer to document-specific notes found on pg. 11, Ongoing Document Requirements found on pg. 12, Additional Recommendations found on pg. 21, and Verification Timeline found on pg. 23 for information about the frequency of verification procedures.

USE *of* APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successful verify that a foreign supplier's food safety processes and procedures meet the requirements of FSVP *(and other applicable regulations)*, must be undertaken. Once complete, the product specific FSVP plan - created by United Safety Agents – will denote a supplier's status on the Title Page of each plan. Importation may occur if the following three parameters are met: 1) the FSVP plan's status does not read "Denied" or other wording denoting that product is not currently approved for import; 2) the date of importation will fall within one calendar year *(365 days)* from the plan's noted "Review End" date, and 3) there are no outstanding issues or changes in the supplier's processes and/or procedures since the noted "Review End" date.

CORRECTIVE ACTIONS

The FSVP Importer will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If the FSVP Importer determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, it will conduct an investigation to determine whether the FSVP should be modified accordingly. Such corrective actions are dependent upon the specific circumstances of the deviation but could include: the complete discontinued use of the foreign supplier, or the discontinued use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.

IDENTIFICATION *of* FSVP IMPORTER

The FSVP Importer will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection: 01) FSVP Importer's Business Name; 02) FSVP Importer's Electronic Mail Address; and 03) The FSVP Importer's FDA acceptable UFI *(Unique Facility Identifier)* such as a DUNS number.

Supplier: La Galvanina S.p.A.

Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: July 23, 2021 Review End: Aug. 16, 2021

UNITED STATES CODE *of* FEDERAL REGULATIONS

The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.

- ☒ **101.** §101.1–101.108. Food Labeling.
- ☐ **106.** §106.1–106.160. Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, & Notifications.
- ☒ **110.** §110.3–110.110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
- ☐ **111.** §111.1–111.610. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- ☐ **112.** §112.1–112.213. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
- ☐ **113.** §113.3–113.100. Thermally Processed Low-Acid Foods Pkged in Hermetically Sealed Containers.
- ☐ **114.** §114.3–114.100. Acidified Foods.
- ☒ **117.** §117.1–117.475. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- ☒ **120.** §120.1–120.25. Hazard Analysis and Critical Control Point (HACCP) Systems.
- ☒ **121.** §121.1–121.401. Mitigation Strategies to Protect Food Against Intentional Adulteration.
- ☐ **123.** §123.3–123.28. Fish and Fishery Products.
- ☐ **129.** §129.1–129.80. Processing/Bottle Drinking Water.
- ☐ **131.** §131.3–131.206. Milk and Cream.
- ☐ **133.** §133.3–133.196. Cheeses & Related Products.
- ☐ **135.** §135.3–135.160. Frozen Desserts.
- ☐ **136.** §136.3–136.180. Bakery Products.
- ☐ **137.** §137.105–137.350. Cereal Flours.
- ☐ **139.** §139.110–139.180. Macaroni & Noodle Products.
- ☐ **145.** §145.3–145.190. Canned Fruits.
- ☐ **146.** §146.3–146.187. Canned Fruit Juices.
- ☐ **150.** §150.110–150.160. Fruit Butters, Jellies, Preserves, and Related Products.
- ☐ **152.** §152.126. Fruit Pies.
- ☐ **155.** §155.3–155.201. Canned Vegetables.
- ☐ **156.** §156.3–156.145. Vegetable Juices.
- ☐ **158.** §158.3–158.170. Frozen Vegetables.
- ☐ **160.** §160.100–160.190. Eggs and Egg Products.
- ☐ **161.** §161.30–161.190. Fish and Shellfish.
- ☐ **163.** §163.5–163.155. Cacao Products.
- ☐ **164.** §164.110–164.150. Tree Nut and Peanut Products.
- ☒ **165.** §165.3–165.110. Beverages.
- ☐ **166.** §166.40–166.110. Margarine.
- ☐ **168.** §168.110–168.180. Sweeteners and Table Sirups.
- ☐ **169.** §169.3–169.182. Food Dressings and Flavorings.
- ☐ **170.** §170.3–170.285. Food Additives.
- ☐ **179.** §179.21–179.45. Irradiation in the Production, Processing and Handling of Food.
- ☐ **190.** §190.6. Dietary Supplements.
- ☐ **501.** §501.1–501.110. Animal Food Labeling.
- ☐ **507.** §507.1–507.215. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- ☐ **570.** §570.3–570.280. Food Additives.
- ☐ **579.** §579.12–579.40. Irradiation in the Production, Processing, & Handling of Animal & Pet Food.

Note: List is not exhaustive. Other regulations may be applicable.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

21 C.F.R. §1.500–§1.514

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- ☒ **§1.500.** What Definitions Apply to This Subpart?
- ☒ **§1.501.** To What Foods Do the Requirements in This Subpart Apply?
- ☒ **§1.502.** What Foreign Supplier Verification Program *(FSVP)* Must I Have?
- ☒ **§1.503.** Who Must Develop My FSVP and Perform FSVP Activities?
- ☒ **§1.504.** What Hazard Analysis Must I Conduct?
- ☒ **§1.505.** What Evaluation for F. Supplier Approval & Verification Must I Conduct?
- ☒ **§1.506.** What Foreign Supplier Verification and Related Activities Must I Conduct?
- ☐ **§1.507.** What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation?
- ☒ **§1.508.** What Corrective Actions Must I Take Under My Foreign Supplier Verification Program?
- ☒ **§1.509.** How Must the Importer Be Identified at Entry?
- ☒ **§1.510.** How Must I Maintain Records of My FSVP?
- ☐ **§1.511.** What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufac turing Practice Regulation?
- ☐ **§1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- ☐ **§1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- ☒ **§1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

This product falls – at least in part – under the jurisdiction of the United States Food and Drug Administration (FDA), and does not qualify for an exemption in Title 21, Code of Federal Regulations, Chapter I, Sub-chapter A, Part 1, Subpart L, §1.501. As the FSVP Importer's Qualified Individual (as the term is defined in §1.503) United Safety Agents – through the actions of this FSVP Plan's identified "Agent(s)" – has performed all actions required by FSVP and has presented this FSVP Plan for the review of this product's FSVP Importer. Please refer to pages 27 through 35 for substantiation of the FSVP QI's / PCQI's qualifications and certifications.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ATTESTATION *of* REVIEW & ASSESSMENT

21 C.F.R., §1.506, (d)(3) provides that *"You may rely on a determination of appropriate foreign supplier verification activities . . . made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities. . . . You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual."* **Please review this FSVP plan in its entirety and document your review below.**

I, _____ certify that I reviewed this FSVP plan on _____ and found
type name *today's date*

its contents to be acceptable.

Reviewer's Name: _____

Reviewer's Signature: _____

Reviewer's Title: _____

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: P&L Imports LLC FDA FEI:

Physical Address: 10051 E Dynamite Blvd. Suite 160 DUNS No.: 11-723-0310

City: Scottsdale State: Arizona, 85262-5242 Country: United States

Mailing Address: 10051 E Dynamite Blvd. Suite 160

City: Scottsdale State: Arizona, 85262-5242 Country: United States

Phone Number: +1 (907) 947-5722 Email Address: info@pandlimports.com

Name *of* Representative*(s)*: Mr. Chris Mohrweis Title: Operations Manager

FOREIGN SUPPLIER &/OR MANUFACTURER *as defined by §1.500*

Company Name: La Galvanina S.p.A. FDA FFR: 10567555272

Manufacturing Address: Via della Torretta N. 2 FDA FEI: 3003097690

City: Rimini Province/Territory: Rimini, 47923 Country: Italy

Office Address: Via della Torretta N. 2

City: Rimini Province/Territory: Rimini, 47923 Country: Italy

Phone Number: +39 0541 751315 Email Address: manuela.pazzaglia@galvanina.com

Name *of* Representative*(s)*: Ms. Manuela Pazzaglia Title: Commercial Rep.

QUALIFIED INDIVIDUAL*(s)* & AGENT*(s)*

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: Aug. 16, 2021

Agent/QI Name: William J. Barber Signature: W. J. Barber

Title: Preventive Controls Qualified Individual. Date: Aug. 16, 2021

SUMMARY *of* REVIEW

Details *of* Product(s)	*Is foreign supplier expected to implement controls for*			**Comments**
	Biological Hazards	**Chemical Hazards**	**Physical Hazards**	
Glavanina Blood Orange Soda in Glass Bottle, non-alcoholic. Product is in Ready-to-Drink condition upon arrival.	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Verified & Approved. — See Addendum.
	☐ FSVP Importer	☐ FSVP Importer	☐ FSVP Importer	
	☐ Disclosure	☐ Disclosure	☐ Disclosure	
	☐ Customer	☐ Customer	☐ Customer	

Preventive Control or Disclosure Rqd.: Per §117, §507, §111 and/or §1.507, Notice is required when FSVP Importer or FSVP Importer's customer will be responsible for controlling hazards. *See "Hazard Analysis & Determination" section(s) and "Addendum" section for additional information.* *Required* *Recommended* *Confirm efficacy of previously applied control(s)*

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES La Galvanina S.p.A.'s Food Safety Plan for Italian Soda in Glass received.
Dated: April 23, 2020.
Prepared By: Matteo Matassoni (QC Manager), Approved by: Massimo Ambrosini (Director & CEO).
Contains Information About: Company Overview, Food Safety Team, Product Description, Distribution, Consumers and Intended Use, Flow Chart: Production Cycle for Soda in Glass, Soda in Glass production Process, Hazard Analysis, Process Preventive Controls, Sanitation Preventive Controls, Food Allergen Preventive Controls, Supply-Chain-Applied Preventive Controls Program, Recall Plan, Corrective Action Records, and Food Safety Plan Reanalysis Report.
Note: Plan is thorough and reviewed at least every 3 years by supplier's primary PCQI.

ON-SITE AUDIT

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES La Galvanina S.p.A.'s BRC Global Standard for Food Safety Issue 8: August 2018 Audit Report received.
Audit Grade: AA. Dated: March 20, 2019.
Re-audit Due Date: March 16 2020. (Note: re-audit postponed due to COVID-19)
Number of Minor Non-conformities: 3. All with corresponding corrective actions.
Previous Audit Grade: AA. Previous Audit Date: March 13, 2018.
La Galvanina S.p.A.'s SGS BRC Issue 8 BRCGS Risk Assessment Report received.
Results: Certificate Extended. Dated: April 03, 2020.
La Galvanina S.p.A.'s IFS Food Version 6.1 Audit Report received.
Audit Grade: 99.13% Dated: April 29, 2020.

SAMPLING OR TESTING RESULTS

☒ *Requested* ☐ *Required* ☐ *Received* ☐ *Reviewed*

NOTES No substantiating information provided by the supplier.

Note: Certificate of Analysis for all FDA-identified biological and chemical hazards requested.

OTHER FOOD SAFETY RECORDS

☒ *Requested* ☐ *Required* ☒ *Received* ☒ *Reviewed*

NOTES La Galvanina S.p.A.'s Good Manufacturing Practices received.
Dated: May 21, 2019. Approved by: PCQI.
Contains Information About: La Galvanina S.p.A.'s manufacuring processes and procedures, and their conformance with Part 117 of Title 21 of the United States Code of Federal Regulations. Specifically: 117.10 Personnel, 117.20 Plant and grounds, 117.35 Sanitary operations, 117.37 Sanitary facilities and controls, 117.40 Equipment and utensils, 117.80 Processes and controls, 117.93 Warehousing and distribution, and 117.110 Defect action levels.
La Galvanina S.p.A.'s Recall Plan received.
Dated: May 28, 2020.

PRODUCT LABELING

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES Product Label received. Label clearly identifies all present allergens. Labeling is in compliance with Part 403(w) of the Federal Food, Drug, and Cosmetic Act in so far as it is not misbranded with respect to the presence of food allergens. See Analysis & Determination of Allergenic Hazard(s) for details.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101.. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all regulations prior to import.

Supplier: La Galvanina S.p.A.

Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: July 23, 2021 Review End: Aug. 16, 2021

VERIFICATION FREQUENCY *for* UPDATED DOCUMENTS

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA's review and determination of the supplier's compliance history and food safety program, receipt of the following food safety documents are recomended accord to their individually-marked time interval.

FACILITY FOOD SAFETY PLAN

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

HACCP PLAN / HARPC PLAN

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

ON-SITE AUDIT RESULTS

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

LABORATORY TESTING RESULTS

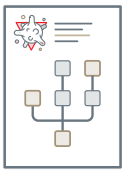
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*

FDA REGISTRATION

- ☑ if a change or update occurs
- ☑ bi-annual basis *(regardless of change)*

FACILITY LICENSE

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *not applicable*



RECALL PLAN

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

PRODUCT LABEL

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

QUALIFICATIONS

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*

IMPLEMENTATION RECORDS

- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☐ on an annual basis
- ☐ on a per-batch/shipment basis
- ☐ *other:*

FSVP QUESTIONNAIRE

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*

NOTES

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

unitedsafetyagents.com/documents

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

21 CFR part 1, subpart L, §1.505(a)(1)(iii)(A)(C), and elsewhere requires that a foreign supplier's compliance history be evaluated, including whether the foreign supplier is the subject of an FDA Warning Letter*(s)*, Import Alert*(s)*, or other FDA compliance action(s) related to food safety. The following constitutes the results of this evaluation.

RESULTS *of* EVALUATION

Date *of* Action	Description *of* Action
October 29, 2013.	FDA FOOD FACILITY INSPECTION. Results: Voluntary Action Indicated. Inspection ID: 853158. Project Area: Foodborne Biological Hazards.
	Note: FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Covers: La Galvanina S.p.A. FEI: 3003097690 Date: Aug. 16, 2021

***Note**: Results may not be exhaustive. FSVP Importer should conduct independent inquiry.*

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	August 14, 2020.	Product and supplier underwent initial FSVP verification.
No. 02	August 15, 2021.	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ANALYSIS & DETERMINATION *of* BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Bacillus cereus*** ☐ ***Clostridium botulinum*** ☐ ***C. perfringens*** ☐ ***Brucella spp.*** ☐ ***Campylobacter spp.*** ☐ ***Pathogenic E. coli*** ☐ ***Salmonella spp.*** ☐ ***S. aureus*** ☐ ***L. monocytogenes*** ☐ ***Trichinella spiralis*** ☐ ***Giardia lamblia*** ☐ ***Shigella spp.*** ☐ ***Other***	0*	3	Biological hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the application of a heat and/or chemical kill-step, implementing and following raw material supplier approval procedures, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes Pasteurization, post bottling to control for hazards posed by biological agents. Details: Process Preventive Control. Microbial Pasteurization carried out by heat treatment on the finished product depending on the type of bottle used. The operators set the correct pasteurizer cycle depending on the bottle format. Pasteurization temperature must exceed 90°C (194°F) for 45 seconds. Process is monitored and registered (time/temperature charts) by PCQI. 02. Supplier utilizes laboratory testing of raw materials, spring water, and finished product to confirm the absence of biological (and chemical) hazards. Details: Each lot of finished flavored soft drinks is checked daily for chemical and biological parameters. External accredited laboratories: CSA Laboratorio, and Università di Camerino. Perimeters: Target: 350 PU. Lower Limit: ≥ 150 PU. Upper Limit: ≤ 900 PU. 03. Production facilities in the syrup room are frequently cleaned and sanitized. ———————NOTE——————— 01. *The FDA does not recognize any biological hazards in reference to this product type. Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified biological hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable. Ex.: Fruit-Flavored Soda. ——————— ———————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ANALYSIS & DETERMINATION *of* CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Drug residues*** ☐ ***Heavy metals*** ☒ ***Industrial chemicals*** ☐ ***Pesticides*** ☐ ***Mycotoxins/Toxins*** ☐ ***Radiological*** ☒ ***Unapproved colors & additives*** ☒ ***Chemical hazards due to mis-formulation*** ☐ ***Other***	1	2	Chemical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – implementing and following appropriate raw material supplier approval procedures, and/or subjecting raw material(s) and/or finished product(s) to laboratory testing. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes raw material supplier approval procedures control help hazards posed by chemicals. 02. Supplier utilizes laboratory testing of raw materials, spring water, and finished product to confirm the absence of chemical (and biological) hazards. Details: Each lot of finished flavored soft drinks is checked daily for chemical parameters. External accredited laboratories: CSA Laboratorio, and Università di Camerino. 03. Supplier closely monitors product's formulation and ingredients with PCQI. 04. Supplier only utilizes an aqueous solution containing Peracetic Acid as a cleaner or sanitizer. Peracetic Acid is used to sanitize bottles prior to filling. Per 21 CFR §178.1010, aqueous solutions containing Peracetic Acid are considered safe to use on food-processing equipment and utensils if they comply with the concentration limits provided (≥100 ppm and ≤200 ppm). Aqueous solution complies with the provided limits. Equipment and utensils are adequately drained before contact with food. 05. Supplier clearly labels/identifies, correctly segregates, and locks all cleaning products. 06. Supplier maintains a list of approved chemicals at the facility for maintenance and cleaning chemicals. 07. All personnel undergo chemical awareness training. 08. Food grade lubricants policy is in place.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified chemical hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable. Ex.: Fruit-Flavored Soda. ——————— ———————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ANALYSIS & DETERMINATION *of* ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Undeclared allergens - Incorrect label*** ☐ ***Undeclared allergens - Cross-contact*** **ALLERGENS** ☐ ***Milk*** ☐ ***Eggs*** ☐ ***Fish*** ☐ ***Shellfish*** *(Crustacean)* ☐ ***Tree nuts*** ☐ ***Peanuts*** ☐ ***Wheat*** ☐ ***Soybeans*** ☐ ***Sesame****	3	3	Allergens themselves can not be directly controlled. However, the presence of allergens – or a given allergen – can be controlled. The presence of allergenic hazards can be effectively controlled through the utilization of a number of control measures, including – but not limited to – staff training for common food allergens, avoiding cross-contact, and proper food labeling. These may be effective methods to ensure that allergens are not ingested by a person who will be experience a negative reaction. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier certifies that: A) there are NO major allergens handled on site. B) a documented allergen control program is in use. C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination. D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area. ———NOTE——— ---------- Labeling Requirements ---------- - Food Allergen Labeling and Consumer Protection Act - ---------- - Nutritional information (not appliance to bulk). - Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). - Quantity of contents (21 CFR 101.7). - Statement of identity (21 CFR 101.3). - Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22). - Ingredient statement if the product has two or more ingredients (21 CFR 101.4). - Presence of major food allergens (21 U.S.C. 343(w)). - Percent juice (21 CFR 101.30), when applicable.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration. Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import. ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable. Ex.: Fruit-Flavored Soda.

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

*Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ANALYSIS & DETERMINATION *of* ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Recontamination with environmental pathogens.*** ☐ ***Bacterial pathogen survival of a lethal treatment.*** ☐ ***Bacterial growth and/or toxin formation due to lack of time / temperature control.*** ☒ ***Recontamination due to lack of container integrity.*** ☐ ***Bacterial growth and/or toxin formation due to poor formulation control.*** ☐ ***Bacterial growth and/or toxin formation due to reduced oxygen packaging.*** ☐ ***Other***	1	2	Hazards posed by ineffective processes or environmental pathways can be controlled by the utilization of Current Good Manufacturing Practices, positively releasing finished product, avoiding cross-contamination, carefully monitoring production process, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Hazard posed by recontamination due to lack of container integrity are controlled through Current Good Manufacturing Practices. 02. Supplier utilizes Pasteurization, post bottling to control for hazards posed by biological agents. Details: Process Preventive Control. Microbial Pasteurization carried out by heat treatment on the finished product depending on the type of bottle used. The operators set the correct pasteurizer cycle depending on the bottle format. Pasteurization temperature must exceed 90°C (194°F) for 45 seconds. Process is monitored and registered (time/temperature charts) by PCQI. Note: If the caps are not correctly applied, the pressure forming inside the bottles because of the heat will make the product spill and the bottles will be discarded by the fill level check machine. 03. Supplier utilizes laboratory testing of raw materials, spring water, and finished product to confirm the absence of biological (and chemical) hazards. Details: Each lot of finished flavored soft drinks is checked daily for chemical and biological parameters. External accredited laboratories: CSA Laboratorio, and Università di Camerino. 04. Product is positively released. Once bottles are sealed there are no significant food safety risks. The operators inspect the containers following the seven points procedure described in the IST. 7.5.08C.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified environmental hazards. _____ ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable. Ex.: Fruit-Flavored Soda. _____ _____

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ANALYSIS & DETERMINATION *of* PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Metal*** ☒ ***Glass*** ☐ ***Extraneous Matter*** ☐ ***Plastics*** ☐ ***Stones*** ☐ ***Wood*** ☐ ***Natural Component of Food*** ☐ ***Other***	1	2	Physical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the utilization of an operational and calibrated metal detector during and/or after the production process, sieving raw material and/or finished product, optical sorting machinery, visual inspection, appropriate and consistent raw material supplier approval methods, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes an operational and calibrated optical inspection machine to control hazards posed by physical contaminates such as metal or glass. Details: Process preventive control. An automatic optical inspection machine inspects the empty glass bottles. The machine is calibrated and validated to detect imperfections, breakages and/or inclusion of foreign objects in the bottles' body, base and sealing surface, and to subsequently discard the bottles. 02. Supplier pressure washes all bottles, with filtered water, prior to filling. Details: Process preventive control. Glass bottles are turned upside down and rinsed with pressurized water. The position of the nozzles and the pressure of the water are calibrated and validated to remove glass fragments from the bottles (if present). 03. Supplier utilizes a Glass and Brittle Plastic procedure to control for the presence of glass (or other physical contaminates in finished product. 04. Supplier utilizes 50 micron filter prior to bottling.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control physical hazards. ——————————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Ready-to-Drink. Category No.: 1. Subcategory: Carbonated. Storage: Shelf-Stable. Ex.: Fruit-Flavored Soda. ——————————— ———————————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: La Galvanina S.p.A.

1.2. Supplier address: Via della Torretta, 2 Rimini, 47923 Italy.

1.3. Products manufactured/supplied: Sparkling and still Mineral Water, Flavored waters, Organic soda and Natural soda.

1.4. Is the supplier certified to a food safety standard and audited regularly? ☐ Yes ☐ No ☒ N/A

GFSI Standard: BRC Issue 8, ISO 14001, OHSAS 18001, ISO 5001, etc.

1.5. Is the standard GFSI benchmarked/recognized? ☐ Yes ☐ No ☐ Other *(see Addendum)*

1.6. Has the supplier provided specifications? ☒ Yes ☐ No

1.7. Has the supplier completed a Supplier Assessment and an Allergen Questionnaire? ☒ Yes ☐ No

1.8. Have the supplier's specifications and/or completed questionnaires been evaluated by USA's PCQI(s)?

☒ Yes ☐ No *PCQI(s):* *C. Innocenti (PCQI)*

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs? ☒ Yes ☐ No

2.2. Does the supplier have SOP in place for each procedure in the production & release of product? ☒ Yes ☐ No ☐ N/A

2.3. Does the supplier have allergen controls in place to prevent cross-contamination? ☒ Yes ☐ No ☐ N/A

3.0 SUPPLIER PERFORMANCE HISTORY

3.1. Does the supplier have a HACCP/PC plan for each product manufactured for the importer? ☒ Yes ☐ No ☐ N/A

3.2. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI(s)? ☒ Yes ☐ No

PCQI(s): *C. Innocenti (PCQI)*

3.3. To the best of USA's knowledge, has the supplier been the subject of a public FDA Alert/Warning Letter?

☐ Yes ☒ No ☐ N/A *Description:* *No, Import Alert & Warning Letter search-results, which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.*

3.4. Has the supplier supplied a product that needed to be recalled for a food safety reason? ☐ Yes ☒ No ☐ N/A

Description: *No, as of this FSVP Plan's Review End date, USA has no knowledge of any recall undertaken by supplier.*

Continued onto next page.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

3.0 SUPPLIER PERFORMANCE HISTORY *(Continued)*

3.5. Has the supplier supplied out of specification product excluding quality issues? ☐Yes ☒No ☐N/A

3.6. Has importer conducted microbiological testing for all lots imported from the supplier? ☐Yes ☐No ☒N/A

3.7. Has any lot tested positive for chemical, physical or biological hazards? ☐Yes ☒No ☐N/A

Description of the incident and the corrective actions taken by the supplier: *No, as of this FSVP Plan's Review End date, USA has no knowledge of any lot/batch testing positive for any FDA-identified hazard(s).*

3.8. Has the supplier provided timely and adequate responses to all requests and issues related to food safety?

☒Yes ☐No *Description:* *Yes, supplier (either directly, or through the FSVP Importer) has provided timely and adequate responses to our inquiries and requests.*

4.0 SUPPLIER APPROVAL

4.1 Have USA's PCQI(s) identified and evaluated the known and reasonably foreseeable hazards for each product imported from the supplier and are there preventive controls in place to adequately control the hazards?

☒Yes ☐No *PCQI(s):* *C. Innocenti (PCQI)*

4.2. After reviewing all hazards and the supplier's performance, have USA's PCQI(s) determined appropriate verification activities that will be conducted and documented on an ongoing basis to verify the preventive controls are effectively controlling the hazard(s)? ☒Yes ☐No

PCQI(s): *C. Innocenti (PCQI)*

4.3 **Is the foreign supplier approved for import into the United States under this FSVP plan?** ☒Yes ☐No

Comments: *Supplier has been verified and their products have been approved for importation.*

Additional Recommendations:

USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

Supplier follows CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

No claims have been made against product.

Overview *of* Foreign Supplier's Commercial Operation

La Galvanina S.p.A. produces mineral water, soft drinks and flavored water in glass. Overview of processes: The production process consists of pipelines and storage tanks of mineral water, depalletizer for empty bottle visual control before entering the washing equipment for glass bottles, washing, sanitizing and rinser of bottles, filling, capping, control for caps presence, labeling, printing the lot number and expiry date, wrapping or cardboard packer and palletizing. For the preparation of soft drinks dissolvers are used to warm for the ingredients, mixing, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers.

La Galvanina S.p.A. operates 2 sites, both IFS certified, located in Val di Meti and Rimini, Italy. Glavanina Blood Orange Soda is made at supplier's Rimini site.

Testing Program & Accreditation

Supplier reports to utilize laboratory testing of raw materials, spring water, and finished product to confirm the absence of biological and chemical hazards. Details: Each lot of finished flavored soft drinks is checked daily for chemical and biological parameters.

Internal lab is segregated from production area and only performs base chemicals and micro analysis. All instrument are calibrated and instruction and methods available and documented. External accredited laboratories: CSA Laboratorio (Accredia no 0181), Merieux Nutriscience (Accredia 0051) and Università di Camerino (Accredia no 0863) are in charge for chemical and microbiological determinations (TBC, P. aeruginosa, Coliforms, Streptococci and S. aureus, yeast and moulds) and censorial analysis. The procedure for laboratory activity is definite in accordance at the QMS. Procedures are in place to ensure that release does not occur until all release criteria have been completed and release authorized.

Supplier & Product Allergen Information

Supplier certifies that: A) there are NO allergens handled on site, B) a documented allergen control program is in use, C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination, D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), tthe Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import.

Packaging Type & Shipping / Handling Requirements

Supplier certifies that packaging is accredited for food use. Ambient shipping and handling requirements. Supplier utilizes a Glass and Brittle Plastic procedure to control for the presence of glass (or other physical contaminates) in finished product.

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

Supplier follows CGMPs and utilizes an established food safety program. Supplier currently holds several GFSI recognized forms of accreditation. These include BRC Issue 8, IFS, ISO 14001, ISO 18001, Organic, NOP, Kosher.

La Galvanina S.p.A.'s BRC Global Standard for Food Safety Issue 8: August 2018 Audit Report received.
Audit Grade: AA. Dated: March 20, 2019.
La Galvanina S.p.A.'s SGS BRC Issue 8 BRCGS Risk Assessment Report received.
Results: Certificate Extended. Dated: April 03, 2020.
La Galvanina S.p.A.'s IFS Food Version 6.1 Audit Report received.
Audit Grade: 99.13% Dated: April 29, 2020.

Close Supplier Monitoring

Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if necessary.

General Comments & Verification Timeline

Supplier follows CGMPs and utilizes an established food safety program. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

NOTE

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

ADDENDUM

NOTE

Labeling Requirements

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways.

The first option for food manufacturers is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement. For example: Vanilla Waffers Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

The second option is to place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients. For example: Contains Wheat, Milk, Egg, and Soy

Food Allergen Labeling and Consumer Protection Act

- Nutritional information (not appliance to bulk).
- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).
- Quantity of contents (21 CFR 101.7).
- Statement of identity (21 CFR 101.3).
- Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22).
- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).
- Presence of major food allergens (21 U.S.C. 343(w)).
- Percent juice (21 CFR 101.30), when applicable.

ADDENDUM

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Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on
05/13/2021

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

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delivered by Lead Instructor

Charles Nolan

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07/09/2020

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Gerald Wojtala, Executive Director
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Susan M. Hays, Executive Director
Association of American Feed Control Officials

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Association of American Feed Control Officials

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Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

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delivered by Lead Instructor

Bob Bauer

completed on

09/14/2018

Robert Brackett, VP and Director
Institute for Food Safety and Health

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Gerald Wojtala, Executive Director
International Food Protection Training Institute

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Joseph Corby, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # d2e9c287

Produce Safety ALLIANCE

Certificate of Training

is awarded to

Claudio Innocent

in recognition for having successfully completed
the Produce Safety Alliance course:

PSA Grower Training Course

Delivered by PSA Lead Trainers and/or PSA Trainers
Cara Fraver, Laura McDermott, Yolanda Gonzalez, Lindsey Pashow

AFDO
ASSOCIATION OF FOOD & DRUG OFFICIALS
SINCE 1896

Class Number
NY-180712-GR
Grower ID Number
50447
Training Date and Location
7/12/2018–7/12/2018
Voorheesville, NY

Joseph Corby
Executive Director, AFDO

Elizabeth A. Bihn, Ph.D.
Produce Safety Alliance Director

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

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delivered by Lead Instructor

Bob Bauer

completed on

05/31/2018

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Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
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delivered by Lead Instructor

Bob Bauer

completed on

09/14/2017

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International Food Protection Training Institute

Joseph Corby, Executive Director
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Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

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in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

delivered by Lead Instructor

Amanda Evans

completed on

07/25/2017

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

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ILLINOIS INSTITUTE OF TECHNOLOGY

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Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

WILLIAM BARBER

in recognition for having successfully completed
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FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Mirasol Mohal

completed on
06/05/2019

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Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

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Foreign Supplier Verification Programs

delivered by Lead Instructor

tina coil

completed on
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Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

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Certificate # 917b0241

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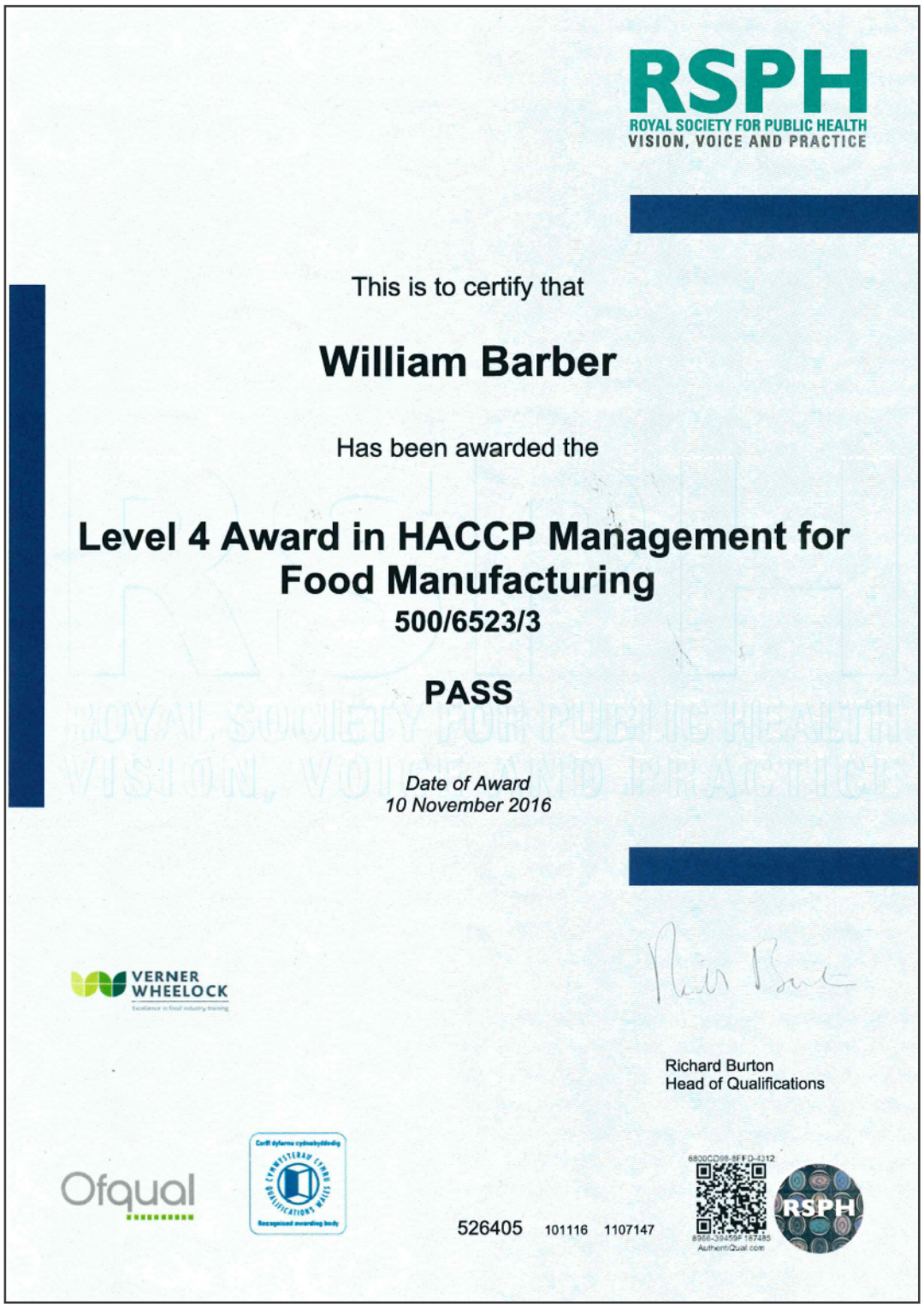

RSPH
ROYAL SOCIETY FOR PUBLIC HEALTH
VISION, VOICE AND PRACTICE

This is to certify that

William Barber

Has been awarded the

Level 4 Award in HACCP Management for Food Manufacturing
500/6523/3

PASS

Date of Award
10 November 2016

VERNER WHEELOCK

Richard Burton
Head of Qualifications

Ofqual

526405 101116 1107147

RSPH

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

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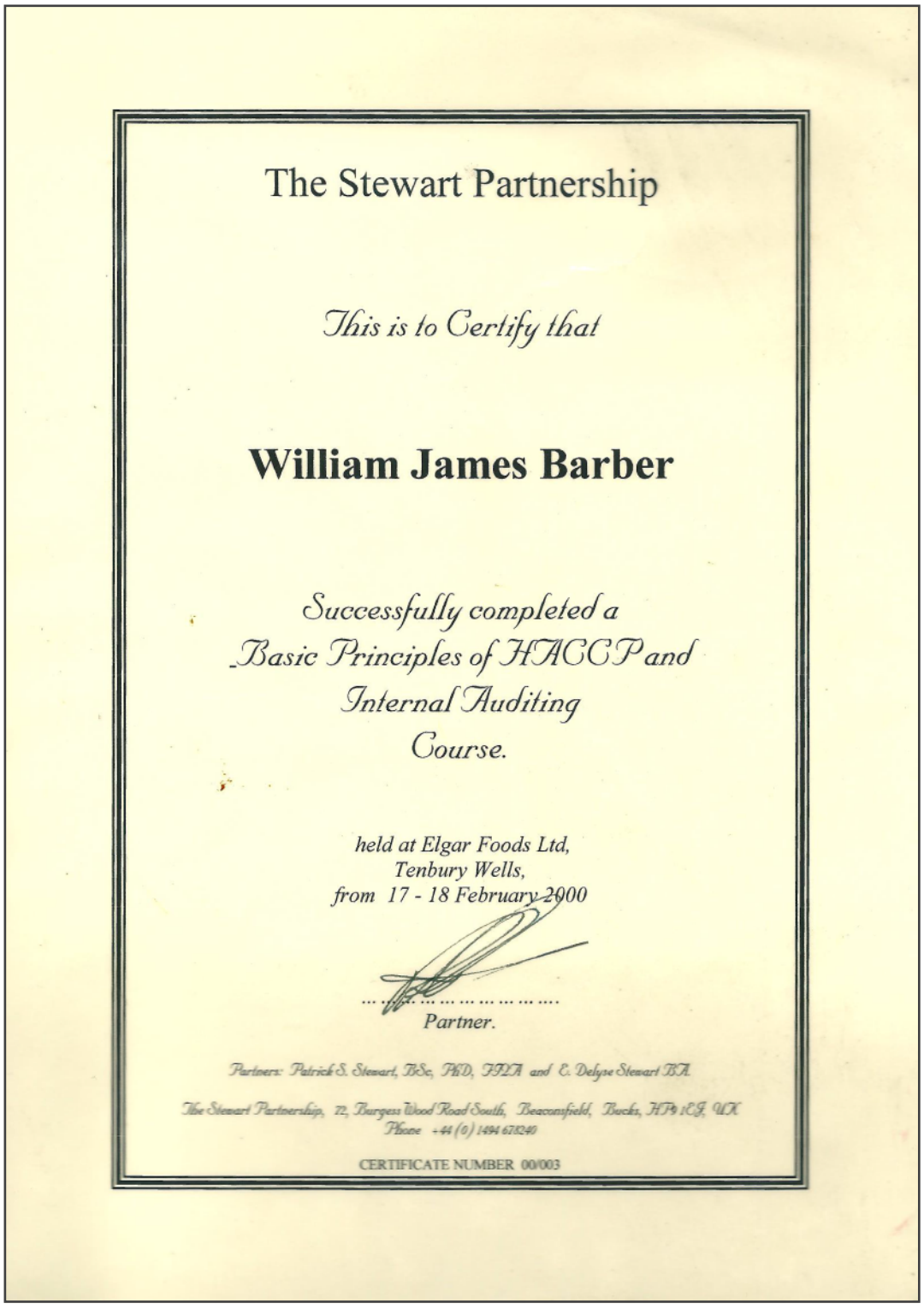

The Stewart Partnership

This is to Certify that

William James Barber

Successfully completed a Basic Principles of HACCP and Internal Auditing Course.

held at Elgar Foods Ltd, Tenbury Wells, from 17 - 18 February 2000

..... *Partner.*

Partners: Patrick S. Stewart, BSc, PhD, FIFDA and E. Delyse Stewart BA

The Stewart Partnership, 72, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 678240

CERTIFICATE NUMBER 00/003

Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

City & Guilds

NATIONAL VOCATIONAL QUALIFICATION

LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS (Q1054402)

IS AWARDED TO

WILLIAM BARBER

THE HOLDER HAS A NUMBER OF FORMAL UNIT CREDITS BY WHICH THIS AWARD WAS ACHIEVED

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64

M Howell
Chairman
The City and Guilds of London Institute

C Humphries
Director-General
The City and Guilds of London Institute

QCA
Qualifications and Curriculum Authority

The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

City & Guilds

CERTIFICATE OF UNIT CREDIT TOWARDS
NATIONAL VOCATIONAL QUALIFICATION
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS

IS AWARDED TO
WILLIAM BARBER

WHO ATTENDED PERSHORE GROUP OF COLLEGES

AND WAS SUCCESSFUL IN THE
FOLLOWING TEN UNITS

CONTROL AND MAINTAIN QUALITY WITHIN MULTI-STAGE MANUFACTURING OPERATIONS	U1024734
RESOLVE PROBLEMS IN MULTI-STAGE MANUFACTURING OPERATIONS	U1024735
MAINTAIN AND IMPROVE HEALTH AND SAFETY WITHIN THE WORKPLACE	U1024736
MAINTAIN AND IMPROVE HYGIENE AND PRODUCT SAFETY WITHIN THE WORKPLACE	U1024737
CONTRIBUTE TO THE ACHIEVEMENT OF ORGANISATIONAL AND PERSONAL GOALS	U1028661
PROVIDE INFORMATION TO SUPPORT DECISION MAKING	U1026144
MONITOR AND MAINTAIN THE HANDLING AND STORAGE OF MATERIALS	U1024742
IMPLEMENT QUALITY ASSURANCE SYSTEMS	U1027820
DEVELOP A FOOD AND DRINK PRODUCT	U1050274

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64

M Howell
Chairman
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Director-General
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R01

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Supplier: La Galvanina S.p.A. Product: Glavanina Blood Orange Soda (Ready-to-Drink)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 23, 2021 Review End: Aug. 16, 2021

SUBSTANTIATING DOCUMENTS

This FSVP plan is based – at least in part – on the following foreign supplier-provided food safety documents. All substantiating documents have been reviewed and assessed by United Safety Agents LLC.

Note All foreign supplier-provided documents are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these documents without the express written consent of the foreign supplier is prohibited. Enclosed documents are meant for review purposes only and are subject to change without notice. Documents may contain non-binding recommendations and are uncontrolled.

Food Safety Plan for Italian Soda

GALVANINA

Developed by the Quality Assurance Department

Date: 23/04/2020

Reviewed by:

_____

Date: _____

Matteo Matassoni
Quality Control Manager, La Galvanina S.p.A.
Primary Preventative Controls Qualified Individual (PCQI)

Approved by:

_____

Date: _____

Massimo Ambrosini
Director and Chief Executive Officer, La Galvanina S.p.A.

Table of Contents

Company Overview

La Galvanina is one of the most modern bottling plants in Italy, where state-of-the-art technology and the use of only the finest glass bottles allow Galvanina Mineral Water to preserve all its precious qualities. La Galvanina is famous in Italy and in the rest of the world not only for Mineral Water, but also for its production of Flavored Waters and Sodas made with fruit juice and natural flavors. La Galvanina has been making Italian Sodas since the early 1900s and it is still a family owned and operated company, so we take special pride in our products. Today, the Galvanina plant in Rimini comprises of two lines, with the production of:

- Sparkling and still Mineral Water;
- Flavored waters;
- Organic soda and Natural soda.

All the products are bottled in glass. This gives the products an excellent protection against alteration of flavor and taste, also defending against chemical, physical and microbiological agents. La Galvanina does not use any kind of preservatives and artificial colors in his products.
The products are made 5 days a week, with two 8-hour production shifts, followed by sanitation operations scheduled by the Quality Control Manager. Cleaning and sanitizing of all processing equipment is conducted per a master sanitation schedule, which also includes cleaning and sanitizing between production runs. Municipal water, which is treated and tested according to the Health Ministry requirements, is used for all cleaning operations. An integrated Pest Control Program is also in place. La Galvanina does not produce any product containing Allergens. As an assurance of this statement, the raw materials chosen are without Allergens. The documentation stating the absence of Allergens in the raw materials purchased is reviewed by qualified internal staff. Furthermore, La Galvanina does not process products containing GMOs (Genetically Modified Organisms). In order to assure that no raw material purchased contains GMOs, the documentation certifying the absence of GMOs inside the raw material is verified by qualified internal staff.

This Food Safety Plan covers the production of Sodas in glass bottles. Other products have separated Food Safety Plans.

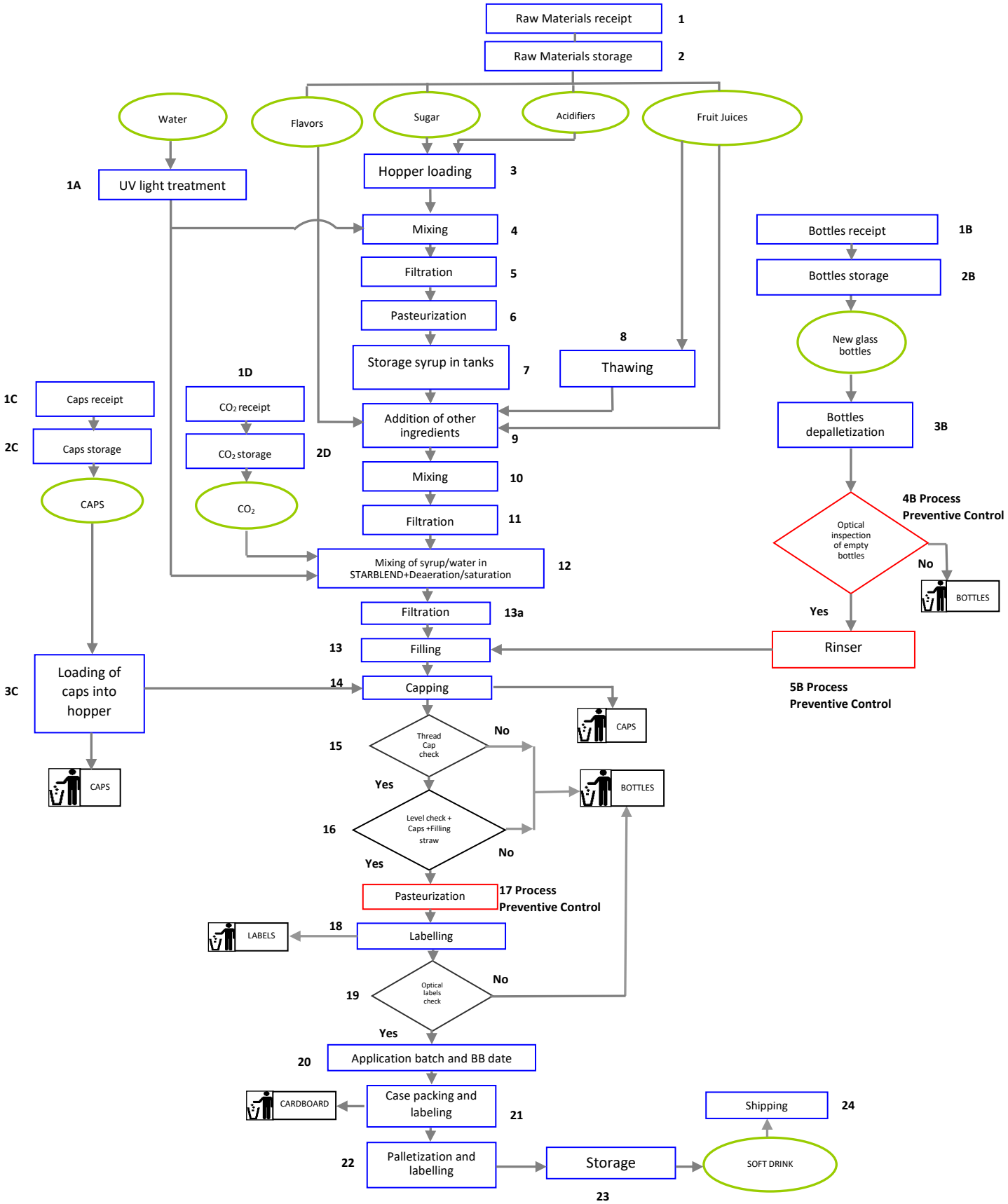
Food Safety Team

Name	Title	Qualifications	Phone
Matteo Matassoni	Quality Control Manager	PCQI, GMP internet training course, MSc in Food science, 15 years of experience in the food industry	+39 0541 751315
Matteo Biguzzi	R&D Manager	PCQI, MSc in Food science, 10 years of experience in the food industry	+39 0541 751315

Lorenzo Valeriani	Quality Assurance Assistant	MSc in Food science, experience with Food Safety and Quality Standards	+39 0541 751315
Roberta De Stefano	Quality Assurance Assistant	MSc in Food science, experience with Food Safety and Quality Standards	+39 0541 751315

Product Description, Distribution, Consumers and Intended Use	
Product Name(s)	Organic Soda and Natural Soda
Product Description, including Important Food Safety Characteristics	Room Temperature, ready to drink, containing fruit and vegetable juices and flavors, carbonated with natural carbon dioxide, acidified with natural acid. pH≤4.0 water activity≥0.85 CO_2≤6.5 g/L Internal pressure: 2.2 – 2.4 bar at 20°C Pasteurized product
Ingredients	Water, Sugar, Fruit Juice, Vegetable Juice, Natural Acid (citric, tartaric, malic, ascorbic), Natural Flavor and Natural carbon dioxide.
Packaging Used	**Food contact packaging materials**: 33.8 fl.oz glass bottle with aluminium cap, 25.4 fl.oz glass bottle with aluminium cap, 16.9 fl.oz glass bottle with aluminium cap, 12 fl.oz glass bottle with aluminium cap. **Non-Food contact packaging materials**: label, corrugated cardboard boxes
Intended Use	The product is sold to an importer who then distributes it to various retailers. Stored at room temperature, ready to drink, no further processing is required.
Intended Consumers	The product is intended for the general public.
Shelf Life	2 years at ambient temperature.
Labeling Instructions related to Safety	Product name, volume, ingredients list, nutritional table, manufacturing company or distributor name, address and contact information, storage and handling instructions.
Storage and Distribution	Do not store in direct light and heat sources. Store in a cool, dry, odorless clean place. Do not freeze. Contents under pressure. Refrigerate after opening and consume within three days. Sedimentation is natural and may occur.
Approved: PCQI	**Date**: 23/04/2020

Flow Chart: Production Cycle for Soda in Glass



Soda in Glass production Process

1. Raw materials receipt

Upon arrival of any raw material, the products are checked by the quality control personnel in line with **Mod. 36A "Check list acceptance of raw materials"**, in case of any NC, the product is not unloaded but immediately returned to the supplier. The QCM approves the attached CoA with a signature and stores it in the lab. Technical specifications of raw materials are kept by the QCM, who requests Allergen and GMO documentation, which is also stored at the quality office.

2. Storage of raw materials

The storage procedures differ depending on the type of product and the supplier's instructions, mainly:

Storage at room temperature:

- RAW MATERIALS IN GENERAL FOR WHICH ROOM TEMPERATURE CONSERVATION IS INDICATED;

Storage in a refrigerated room from 0 ° C to + 4 ° C:

- NATURAL FLAVORS
- FRUIT JUICES
- RAW MATERIALS IN GENERAL FOR WHICH REFRIGERATED TEMPERATURE CONSERVATION IS INDICATED;

Storage in a refrigerated room at - 18 ° C:

- ALL RAW MATERIALS WHICH ARE DELIVERED FROZEN BY THE SUPPLIER.

The temperature-controlled rooms are equipped with a light signal alarm device indicating the non-complete closing of the doors. The temperature in the rooms is continuously controlled by an alarm system that goes off when the temperatures exceed the set values: -18°C for the negative and + 4°C for the positive. Moreover, for continuous monitoring purposes, the alarm is connected to an operator's mobile phone, which allows the monitoring of the rooms also outside of working hours. All raw materials are stored in suitable areas/facilities and stored on plastic pallets and/or metal shelves. Organic raw materials are stored in specific identified areas in order to avoid mixing with non-organic products. The company applies the "first in/first out" principle to storage.

3. Hopper loading

In the syrup room there is a hopper with a feeding screw, which carries the sugar inside the mixer for the preparation of the so-called "base". The operator, after consulting the production order provided by the PM, collects the sugar from the warehouse and after visual inspection of the expiration date and packaging, he/she opens the package and performs a further visual check in order to ensure it is free of foreign bodies. In the event that foreign bodies are found, the worker will remove the bag, set it aside and label the bag with the Non-Conformity Card in order to warn the QCM about the anomaly (see **PRO 8.5.01 - "Non-conformity/Preventive Corrective Actions"**). If, on the contrary, there are no foreign bodies found, the worker proceeds with transferring the sugar in the hopper.

1A. UV light treatment

The Water passes through an UV light system to remove any microorganism and improve the cleanliness of the machines and pipes.

4. Mixing

Treated water is introduced into the Mixing tank for the preparation of the "base" (water, sugar and citric acid), or mineral water depending on the drink specifications that are found on the

operative ins. For each recipe, a specific "base" is prepared. Thanks to a mixer inside the machine, the dissolution of sugar is facilitated and the water is brought to a temperature of 25-30°C.

5. Filtration

Before the pasteurization process, the "base" is filtered through a series of filters to retain any suspended particles. Specifically, the "base" is inserted at the feed of the tube bundle housing containing a 400 µm single bag filter, thereafter in the plate exchanger input where there are two other parallel housings which contain 50 µm bag filters followed by a housing for 50 µm absolute candle filter in series.

6. Pasteurization

Within the flash plate pasteurizer, the sugared syrup undergoes a heat treatment of ≥90°C for 45 seconds for soft drinks. The operator records the pasteurization times and temperatures on **MOD.10**. The Process data is then automatically recorded in the pasteurizer PC and can be printed as needed. At this stage, the microbial charge of the "base" is abated. After being pasteurized, the syrup is automatically sent to the storage tank.

7 Syrup storage in tanks

The pasteurized "base" is conveyed into specific tanks, in which all the other ingredients that make up the recipe will eventually be added and mixed. The syrup remains stored in the tanks until bottling. Between March and November, the maximum storage time for the syrup is 48 hours, meanwhile in the period between December and February the maximum storage time for the syrup is 72 hours.

8 Thawing

Concentrated fruit juices are generally frozen, hence before production they must be thawed as stated in **IST.7.5.214 "thawing of raw materials"**. The unused juice is refrozen and pasteurized together with the sugared syrup before the next use.

9 Addition of other ingredients

Other ingredients (aromas, juice, extracts), which are stored in tanks, are added to the "base" as indicated in the recipe. The authorized personnel collect all the ingredients from the warehouse and check the expiration date and integrity and cleanliness of the packaging, open the box, and perform a further visual check to ensure there are no foreign bodies inside. In the event that foreign bodies are found, the worker will remove the box/container/drum, set it aside and label the package with the Non-Conformity Card in order to warn the QCM about the anomaly (see **PRO 8.5.01** – "Non-conformity/Preventive Corrective Actions"). If, on the contrary, there are no foreign bodies found, the worker proceeds with transferring the required ingredients to the tank.

10 Mixing

In the storage tank, another mixing process takes place for at least 15 minutes in order to blend the "base", the sugared syrup and the additional ingredients that make up the recipe.

11 Filtration

In order to retain any suspended particles, the mixed syrup is then subjected to filtration with a bag filter with sizes of 250 µm to 400 µm.

12 Syrup/water Mix in starblend + deaeration/saturation

The "Starblend" is located in the bottling department: it is an automated system that mixes the water-prepared syrup, previously deaerated and saturated with Carbon dioxide (CO_2), depending on the set recipe. The product obtained by mixing is then sent to the filling machine.

13a Filtration
The drink undergoes a filtration process to retain any foreign bodies thanks to a metal sieve with 0.5mm meshes. Before the line sanitization operations, operators dismantle the sieve and check its compliance and presence of any foreign bodies. The intervention is recorded in MOD.48 CCP2-CCP3.The presence of foreign bodies caught by the sieve is reported to the QCM.

1.B Bottles receipt
The bottles are palletized on wooden pallets, divided into several layers. Each layer is separated by plastic pallet sheets, except for the last layer which is covered with a cardboard cover. All the pallets of bottles are wrapped with film in order to prevent the bottles from being contaminated, or getting dirty, by environmental factors. At each delivery, the packaging is checked to verify the compliance, integrity and cleanliness of the delivered bottles, together with the compliance to the bill of lading and all verifications are recorded on the MOD. 36. In case of NC on the purchased goods, the load is rejected. All crates are handled carefully by well-trained personnel to avoid damage.

2.B Bottles Storage
Bottles are stored outdoors on the company premises, in a dedicated area. If the storage of new bottles exceeds 12 months, the depalletizer workers must send these bottles to the bottle washing machine before moving on to the rinsing machine. Otherwise, new bottles go directly to the rinsing machine.

3.B Bottles Depalletization
"LA GALVANINA S.p.A.", in Rimini, uses only glass containers. Bottle pallets are positioned on the depalletizer by the forklift operator. Each new bottle pallet contains a manufacturer's sheet with the indications for traceability of the production lot number. This sheet is delivered daily to the Shipping Office by the depalletizer personnel, together with the identification data of the new bottles used and the related checks recorded on the file (MOD 55).

4.B Empty bottle optical inspection
Before the rinsing and filling process, all empty bottles go through an optical inspection machine. This step is essential in order to detect the presence of foreign objects inside, along the sides and at the bottom of the bottle; moreover, cracks on the bottle finish or threads, liquid residue and any external defect (scuffing) are detected. Those faulty bottles are removed by means of a pneumatic ejector and diverted to a closed section of the conveyor belt where they will then be removed by the operator. The personnel applies **IST.7.5.04/A** for calibration of the machine and records the checks on **MOD. 54 CCP1_L1**.

5B. Rinsing machine
New bottles (or those washed in the bottle washing machine) are rinsed in a rinsing machine following this method: sanitization with a mix of water and peracetic acid in the first part of the carousel and a second rinsing with treated water in the second part of the carousel. The operator records the machine control operations and the sanitizing product concentration on the **MOD. 53**. The machine is set up by the operators and checked daily (**ISTR 7.5.02**) by the laboratory technician to verify:
- the presence of sanitizing products in the first part of the carousel;
- the absence of sanitizing products on the bottles washed in the second part of the carousel.

These checks are recorded in the **MOD. 115**.
After being washed the bottles are moved along the line by conveyor belts protected by a stainless steel cover.

1.D CO_2 Receipt
The CO_2 is delivered by means of a special tanker from a supplier. At the time of unloading, a lab worker verifies the integrity of the safety seal and the accompanying documentation (CoA), later reviewed and validated by the QCM. This verification is recorded in the **MOD. 36/A**.

2.D CO_2 Storage
The CO_2 is stored in two tanks and is carried to the filling department through a pipeline.

13. Filling
The bottles move on to the filling machine to be filled with soft drinks.
Prior to the filling phase, the operator checks there is no residue of detergent or sanitizing products, used in the sanitizing procedures, with indicator strips, recording the operation on the **MOD. 48 CCP2-CCP3**.
During production, operators check the volume using a certified scale, as specified in **MOD. 229**, also the gasification is checked with a calibrated aphrometer, this check is recorded in **MOD 54 A** and the Brix value, measured with a calibrated refractometer, is recorded in **MOD.274**. In the event of bottles exploding during the filling phase, the operating procedure followed is stated in **IST. 7.5.29** "Instructions in case of bottle explosion in the filling machine". The explosions are recorded by the operator in the **MOD.54** reporting date and time. There is a stainless steel cover from the filling machine entrance all the way to the capping machine to prevent possible physical contamination of the product.

1.C Cap Receipt
Every delivery is checked for conformity with the order, integrity and cleanliness of the delivered crates, and compliance with the shipping documents, these checks are registered in the **MOD. 36**. In the event of a NC with the goods, the delivery is rejected. All the crates are handled carefully by well-trained personnel to avoid damage.

2.C Cap Storage
The caps are stored in an appropriate warehouse, separate from the rest of the production area. The warehouse workers carefully follow the GMPs for handling in order to avoid breakage of the protective packaging and consequent contamination of the caps. The QCM approves the attached CoA with a signature and archives it at the lab. The technical data sheets and the documents certifying the caps are suitable to come in contact with food or beverage, previously approved by the QCM/QAM, are filed at the quality assurance office.

3.C Loading caps into hopper
The operator, after consulting the production order provided by the PM, takes the required caps from the warehouse, recording the operation in **MOD. 49 "Daily cap picking list".** The caps are picked by the operator following the GMP during the handling phases and are placed inside a storage tank equipped with a pneumatic transport system, which utilizes ozonized pressured air. The caps are conveyed to a conical bottom hopper with a rotating disc for the vertical distribution of the caps. The caps are automatically sent to the capping machine via a conveyor belt provided with an orientator to give the correct alignment.

14. Capping
The filled bottles move on directly to the capping machine installed on the filling machine. The operators for each production verify correct closure by means of a torque meter by which the opening force is measured. The data resulting from the check is recorded in the **MOD.47**.

15. Cap thread check
The bottles filled and capped pass through an automatic inspector, which thanks to a series of optical viewers, can monitor the formation of the cap threads on the mouth of the bottle. The machine inspects the correct closure of the cap from 8 different angles verifying:
- Thread length;
- Thread depth;
- Sealing circumference;
- Cap height;

• Anti tampering ring.

All non-conforming bottles are automatically ejected from the line by the machine, using a pneumatic piston, onto a storage belt. All bottles are then disposed of in a bin for glass.

16. Level + Bottle Cap Check + Nozzle Detector

The bottles pass through an electronic system to check the bottle fill level and the presence/absence of the cap. There is also a magnet to check if any metal filling nozzles are present. The operators set the machine at the beginning of production, depending on the bottle size used. From these checks, any non-conforming bottles are discarded by means of a pneumatic ejector and diverted to a closed section of the conveyor belt where they will be removed by the operator. The magnet blocks the belt if a metallic filling nozzle is detected inside a capped bottle.

17. Pasteurization

Once the bottles have been filled and capped, they undergo a pasteurization process inside a tunnel pasteurizer with sprinklers. Each bottle format corresponds to a specific program. Each program has set pasteurization cycles, with relative duration times and operating temperatures. All non-alcoholic drinks are subjected to a treatment of 350 U.P. The critical limits to be monitored and which must not be exceeded at this stage of the process are two:

- **Lower critical limit**: ≤150 UP compared to the programmed P.U. (Pasteurization Units): the product is identified as Nonconforming and then moved to the "non-saleable product warehouse" waiting for destruction/disposal.
- **Top critical limit**: ≥900 UP compared to the programmed P.U. (Pasteurization Units): The product is identified as Nonconforming and then moved to the "non-saleable product warehouse" awaiting for organoleptic re-evaluation. After passing the laboratory test and microbiological analysis, the product is evaluated as compliant and marketed.

The pasteurization machine is equipped with an automatic pasteurization recording system, which prints out the reports of the pasteurization cycles at set intervals.
The following day, the documentation is collected by the laboratory personnel; this documentation is checked, stamped and archived in a specific folder in the Laboratory/Quality Assurance Office. The QCM requests the lab technicians, to place a digital thermometer (Data Logger) on a bottle, this thermometer records, at set intervals, the pasteurization temperatures. The worker on duty continuously inserts the digital thermometer into the pasteurizer.
The digital thermometer software generates a graph of the day's pasteurization cycles, which is checked by the laboratory workers (data download is carried out daily).

18. Labeling

Once filled and capped, the bottles continue along the belt to the labeling machine for the label attachment, which specify the product and the format, as well as the production lot number and the Best Before Date (**MOD 15**).
The workers must check the production order. **MOD.78** and prepare the labels to be used accordingly with the "Product Sheets" **MOD.15**.
All the activities and checks of the labeling process are recorded on **MOD.52** by the workers. The operators must collect a sample of the finished product every 20 minutes, and the final quantity must not be less than 2 liters by the end of production, these samples are needed for analytical tests in the laboratory.

19. Label application check

The labeled bottles move on to an optical check that verifies the presence of the label, the correct alignment, the use of the correct references. The operators set the machine with saved programs to monitor the reference during production. The machine blocks the system if it sequentially detects 5 nonconforming bottles (no label, upside-down label, wrong reference).

20. Lot Number and Best Before Date

The Production Lot Number and the Best Before Date are printed on the cap with a printer. The operators set the lot coding in accordance with the instructions given in (**MOD.15**).

21. Packaging and labeling

The bottles are packed in cartons which have the information about the product, the Production Lot Number and the Best Before Date attached. All activities and checks on the packaging process are recorded in **MOD. 52** by the workers.

22. Palletizing and labeling

The crates are sent to the palletizer which automates the production of the pallet on which a plastic film is applied to ensure its stability. Two logistics labels are attached, indicating the SSCC (indicod) codes, which summarize the contents of the pallet (number of crates, product, date of production, lot number, best before date). These labels are printed by the LM.

23. Storage

The pallets are taken by the workers and stored in the warehouse. The Warehouse Manager decides on the goods storage areas and the layout of the lots by applying the principle first in first out.

24. Shipping

Every container is inspected before shipment, following the seven-points procedure described in the **IST. 7.5.08C**.

Hazard Analysis

Hazard identification (column 2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

E (EMA) = Economically motivated adulterations

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
1 Raw material receipt (Concentrated Fruit Juices)	B	Presence of yeasts, molds, lactic bacteria, *Escherichia coli, Salmonella*.	X		Presence of microorganisms that may affect food safety or alter the organoleptic properties on the finished product. *E. coli* and *Salmonella* are identified as a potential hazard for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry"* by the FDA. The company has a policy to work only with suppliers certified by at least one GFSI approved standard.	**Process Preventive Control** Subsequent pasteurization		**X**
	C	Patulin (apple juice)		X	Although exposure over time to high levels of patulin may pose a health hazard (FDA, Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition), there is not enough data to indicate the incidence of any adverse health effects in humans and no unequivocal documented patulin derived food poisoning outbreak. The apple juices used are tested every year for patulin			

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
					levels, which must not exceed 50 ppb (FDA, CPG Section 510.150).			
		Ochratoxin A		X	The raw materials that present the highest occurrence and concetration of ochratoxin A are: cereals, coffee and grapes, especially black varieties (JØrgensen, 2005). Of these products, the company is currently using only a white-grape juice, which is tested yearly for the presence of ochratoxin a. Berries juices, caramelized sugars and infusions are also sampled and tested every year for the presence of ochratoxin A. All the suppliers are required to guarantee that their product is safe for consumption and are certified by at least one GFSI approved standard. No ochratoxin has ever been found in any raw material purchased by the company.			
		Allergens		X	The company policy establishes to not introduce nor process any raw material containing allergens. Every supplier is required to provide a certificate stating that the raw materials purchased contain no allergens. All the suppliers are certified by at least one GFSI approved standard.			
	P	None						

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	E	None						
1 Raw material receipt (granulated sugar, liquid caramel)	B	None						
	C	None						
	P	Foreign bodies: soil, rock fragments, hard plant material (≥7mm, ≤25mm).		X	The occurrence of such fragments is very low and there has never been a food safety related problem derived from these fragments. Moreover the sugar syrup is filtered, prior to the pasteurization, with 50 µm filters, to decrease its turbidity.			
	E	None						
1 Raw material receipt (Flavors)	B	None						
	C	None						
	P	None						
	E	None						
1 Raw material receipt (Treated–softened, Source Water)	B	Coliforms, faecal streptococci, *Pseudomonas aeruginosa, Staphilococcus aureus.*	X		Presence of microorganisms that may affect food safety or alter the organoleptic properties on the finished product. The water is analyzed weekly for the presence of microorganisms, as described in the **TAB. 7.5.06**.	**Process Preventive Control** Subsequent pasteurization		**X**
	C	None						
	P	None						
	E	None						
1 Raw material receipt (organic acids e.g. citric acid,	B	None						
	C	None						
	P	None						

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
tartaric acid, ascorbic acid)	E	None						
1D Raw material receipt (Processing Aid Gases: Carbon Dioxide)	B	None						
	C	None						
	P	None						
	E	None						
1C Primary packaging receipt (caps)	B	None						
	C	None						
	P	None						
	E	None						
1B Primary packaging receipt (empty bottles)	B	None						
	C	None						
	P	Damaged bottles. Foreign bodies inside the bottles: glass fragments (≥7mm, ≤25mm).	X		The bottles are checked by an automatic optical inspection machine further down the line, to ensure that they are intact. The bottles are also subsequently rinsed with pressurized water to remove any glass fragment that could pose a health hazard.	**Process Preventive Control** Subsequent automatic optical inspection and rinsing.		**X**
	E	None						
2 Raw material storage (room temperature)	B	None						
	C	None						
	P	None						
	E	None						
2 Raw materials storage (refrigerated 0-5°C)	B	Pathogen growth: *Escherichia coli, Salmonella*.		X	These refrigerated ingredients do not support pathogen growth. All the incoming goods are checked for packaging integrity and suitable			

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
					expiration date, as described in the IST. 7.5.08 A.			
	C	None						
	P	None						
	E	None						
2 Raw material storage (frozen -18°C)	B	Pathogen growth: *Escherichia coli, Salmonella*.		X	These frozen ingredients don't support pathogen growth. All the incoming goods are checked for packaging integrity and suitable expiration date, as described in the IST. 7.5.08 A.			
	C	None						
	P	None						
	E	None						
2B Primary packaging storage (empty glass bottles)	B	None						
	C	None						
	P	None						
	E	None						
2C Primary packaging storage (caps)	B	None						
	C	None						
	P	None						
	E	None						
2D Raw material storage (Processing Aid gasses: Carbon Dioxide)	B	None						
	C	None						
	P	None						
	E	None						
3 Hopper loading	B	None						
	C	None						

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(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	P	Physical contamination: hard plastic fragments, metal fragments (≥7mm, ≤25mm).		X	Fragments of packaging material can fall inside the hopper and contaminate the syrup. The product is filtered multiple times before filling, using filters with ≤1mm mesh.			
	E	None						
1A UV light treatment	B	*Pseudomonas aeruginosa, Escherichia coli*		X	The QC department carries out a periodic analysis of the Water to check for the presence of pathogens (TAB. 7.5.06). The analysis have always shown negative results. The UV lamps are installed to further improve the cleanliness of the machines and pipes.			
	C	None						
	P	None						
	E	None						
4 Mixing	B	Microbiological proliferation: *Escherichia coli, Salmonella*.		X	*E. coli* and *Salmonella* are identified as a potential hazard for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry"* by the FDA. The production facilities in the syrup room are frequently cleaned and sanitized (see IST 7.5.28).			
	C	None						
	P	None						
	E	None						

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
5 Filtration	B	None						
	C	None						
	P	Foreign bodies: soil, rock fragments, hard plant material (≥7mm, ≤25mm).		X	The purpose of this step is to remove the impurities contained in sugar, which effect the turbidity of the finished product, but are of no threat to food safety. 50 µm filters.			
	E	None						
6 Pasteurization	B	Pathogen presence: *Escherichia coli*, *Salmonella*.		X	The purpose of this step is to stabilize the bacterial load in the "base" (sugar syrup) and eventual juices coming from containers already opened during previous productions. The set pasteurization temperature (≥90°C for soda ≥98°C for tea) is monitored and registered (time/temperature charts).			
	C	None						
	P	None						
	E	None						
7 Syrup storage in tanks	B	Microbiological proliferation: *Escherichia coli, Salmonella*.		X	*E. coli* and *Salmonella* are identified as a potential hazard for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry"* by the FDA. The production facilities in the syrup room are frequently cleaned and sanitized (see IST 7.5.28).			
	C	None						

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	P	None						
	E	None						
8 Juice thawing	B	None						
	C	None						
	P	None						
	E	None						
9 Addition of other ingredients	B	None						
	C	None						
	P	None						
	E	None						
10 Mixing	B	None						
	C	None						
	P	None						
	E	None						
11 Filtration	B	None						
	C	None						
	P	Foreign bodies: gasket fragments (≥7mm, ≤25mm).		X	The product is always inside a pipeline and there is no risk of contamination by foreign bodies. At this step, the filter serves the sole purpose of removing possible tiny particles from the gasket wear. The dimension of the filters is 400 µm.			
	E	None						
12 Mixing "base" / water in starblend + deareation / saturation	B	*Escherichia coli*, *Salmonella.*	X		*E. coli* and *Salmonella* are identified as a potential hazards for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for*	**Process Preventive Control** Subsequent pasteurization		**X**

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
					Human Food: Draft Guidance for Industry" by the FDA.			
	C	Sanitizer: Peracetic acid		X	Residues of peracetic acid used in the sanitization operations may exceed the safe limits. On the *CFR Title 21, Chapter I, Subchapter B, Part 178, Subpart B, §178.1010*, aqueous solutions containing peracetic acid are considered safe to use on food-processing equipment and utensils if they comply with the concentration limits provided (≥100 ppm and ≤200 ppm). The equipment and utensils must be adequately drained before contact with food.			
	P	None						
	E	None						
13a Filtration	B	None						
	C	None						
	P	Foreign bodies: gasket fragments (≥7mm, ≤25mm).		X	The product is always inside a pipeline and there is no risk of physical contamination. At this step, the filter serves the sole purpose of removing possible tiny particles from the gasket wear. Filter mesh size: 0,5 mm.			
	E	None						
3B Depalletization of new bottles	B	None						
	C	None						
	P	Glass fragments (≥7mm, ≤25mm).	X		During the depalletization and bottle transport, the glass bottles can break and glass	**Process preventive control** Subsequent bottle rinsing.		**X**

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
					fragments can go inside other intact glass bottles.			
	E	None						
4B Empty bottle optical inspection	B	None						
	C	None						
	P	Bottles' sealing surface/rim broken or nor correctly shaped, bottles' body and base containing defects or foreign objects (≥1mm) that can lead to bursts.	X		The automatic optical inspection machine is needed to discard non conforming bottles.	**Process preventive control** An automatic optical inspection machine inspects the empty glass bottles. The machine is calibrated and validated to detect imperfections, breakages and/or inclusion of foreign objects in the bottles' body, base and sealing surface, and to subsequently discard the bottles.	**X**	
	E	None						
5B Rinsing Machine	B	None						
	C	Sanitizer: Peracetic acid		X	On the *CFR Title 21, Chapter I, Subchapter B, Part 178, Subpart B, §178.1010*, aqueous solutions containing peracetic acid are considered safe to use on food-processing equipment and utensils if they comply with the concentration limits provided (≥100 ppm and ≤200 ppm). The peracetic acid is also rinsed with mineral water and its decomposition products, acetic acid and hydrogen peroxide, are both present in the GRAS Substances (SCOGS) Database. There are no cases, in the scientific literature (PubMed), in the *FDA Archive for Recalls,*			

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
					Market Withdrawals & Safety Alerts or on the EU RASFF portal, of food intoxications caused by the ingestion of peracetic acid residues.			
	P	Glass fragments (≥7mm, ≤25mm).	X		The rinsing machine is needed to remove fragments of glass from the bottles, that can be introduced in the previous depalletization step.	**Process preventive control**. The glass bottles are turned upside down and rinsed with pressurized water. The position of the nozzles and the pressure of the water are calibrated and validated to remove the glass fragments from the bottles.	**X**	
	E	None						
13 Filling	B	*Escherichia coli*, *Salmonella.*	X		*E. coli* and *Salmonella* are identified as a potential hazards for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry"* by the FDA.	**Process Preventive Control** Subsequent pasteurization		**X**
	C	Sanitizer: Peracetic acid		X	On the *CFR Title 21, Chapter I, Subchapter B, Part 178, Subpart B, §178.1010*, aqueous solutions containing peracetic acid are considered safe to use on food-processing equipment and utensils if they comply with the concentration limits provided (≥100 ppm and ≤200 ppm). The equipment and utensils must be adequately drained before contact with food.			
	P	None						
	E	None						
	B	None						

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
3C Loading caps into hopper	C	None						
	P	None						
	E	None						
14 Capping	B	Growth of pathogens like *Escherichia coli,* molds and yeasts due to loss of CO_2, rise of pH and contamination with external air.	X		The product is subsequently pasteurized. If the caps are not correctly applied, the pressure forming inside the bottles because of the heat will make the product spill and the bottles will be discarded by the fill level check machine.	**Process Preventive Control** Subsequent pasteurization		**X**
	C	None						
	P	None						
	E	None						
15 Cap thread check	B	None						
	C	None						
	P	None						
	E	None						
16 Level + Bottle Cap Check + Nozzle Detector	B	None						
	C	None						
	P	None						
	E	None						
17 Pasteurization	B	Microbial contamination of the final product: *Escherichia coli*, *Salmonella.*		X	*E. coli* and *Salmonella* are identified as a potential hazards for beverages containing fruit juice in the *"Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry"* by the FDA.	**Process Preventive Control** Microbial stabilization carried out by heat treatment on the finished product depending on the type of bottle used. Target: 350 PU I.L. ≥ 150 PU U.L. ≤ 900 PU	**X**	

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
						The operators set the correct pasteurizer cycle depending on the bottle format.		
	C	None						
	P	None						
	E	None						
18 Labeling	B	None						
	C	None						
	P	None						
	E	None						
19 Label application check	B	None						
	C	None						
	P	None						
	E	None						
20 Application of lot and best before date	B	None						
	C	None						
	P	None						
	E	None						
21 Case packing and labeling	B	None						
	C	None						
	P	None						
	E	None						
22 Palletization and labeling	B	None						
	C	None						
	P	None						
	E	None						

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
23 Storage	B	None						
	C	None						
	P	None						
	E	None						
24 Shipping	B	Contamination of the product's packaging with moulds and yeasts.		X	The product is sealed inside the bottles and there are no significant food safety risks. The operators inspect the containers following the seven points procedure described in the IST. 7.5.08C.			
	C	None						
	P	None						
	E	None						

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Process Preventive Controls

Process Preventive Control Step	Hazard(s)	Operating Limits / Critical Limits	Monitoring		Corrective Action	Verification	Records
			What	How / Frequency / Who			
4B Optical inspection machine	**Physical**: Bottles' sealing surface/rim broken or nor correctly shaped, bottles' body and base containing defects or foreign objects (≥1mm) that can lead to bursts.	Operating Limits: defects ≥1mm and foreign objects in the body and base ≥1mm. Critical Limits: defects ≥2mm and foreign objects in the body and base ≥2mm.	The inspection machine correctly discards defective and damaged bottles.	The operators check the correct functioning of the inspection machine at the start of the production and before a bottle format change, using clearly marked sample bottles. The results of the monitoring is recorded in the **MOD. 54 CCP1_L1**. All the operators performing the monitoring receive specific training once a year (see the training program and registry attached).	**1)** If, during the monitoring, a non-compliance is found, the operator stops the production line (following the **TAB. 7.5.06**). The Quality Control department, with the supervision of the PCQI, identifies and marks all the affected product (usually all the goods produced from the latest compliant check) with the **MOD. 08** and implements and records the Corrective Action by filling the **MOD. 07**, following the **PRO. 8.5.01**. The production line restarts only after the Corrective Action is implemented and approved by the QCM. **2)** If the NC is critical for Food Safety, all the goods produced from the latest compliant check are destroyed. The Food Safety Team, together with the Quality Control and Quality Assurance departments, reviews the preventive control, the working parameters of the machine, the calibrations and its validation and, if necessary, modifies the procedure appropriately and perform a new validation. The Food Safety Team records its actions and verifications in the **MOD. 07** and performs a Root Cause Analysis, following the **PRO. 8.5.01**.	**1)** The laboratory technicians check daily that the operators perform the preventive control correctly and sign the **MOD. 54 CCP1_L1** for approval. The Quality Control department performs a documentary check weekly, signing the **MOD. 54 CCP1_L1** and, eventually, the **MOD. 07**, for approval. **2)** The Food Safety Team reviews the completed **MOD. 07** and verifies the efficacy of the Corrective Action/s implemented and the Root Cause Analysis, filling and signing the **MOD. 07** for approval, as described in the **PRO. 8.5.01**. The PCQI reviews the filled **MOD. 07** and signs it for approval within 7 days from its creation, as described in the **PRO. 8.5.01**. The optical inspection machine is calibrated and validated to detect glass fragments and subsequently discard the bottles, following the specific validation module (see attached). All the operators and technicians performing the monitoring receive specific training once a year (see the training program and registry attached). The PCQI reviews all the records within 7 working days from their creation.	**MOD. 54 CCP1_L1** **MOD. 07** **MOD. 08** **Validation Modules** **Training Program and Registry.**

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Process Preventive Control Step	Hazard(s)	Operating Limits / Critical Limits	Monitoring		Corrective Action	Verification	Records
			What	How / Frequency / Who			
5B Rinsing Machine	**Physical:** Glass fragments (≥7mm, ≤25mm).	Operating Limits: rinsing machine nozzles centered and water pressure ≥1 and ≤2.5 bar. Critical Limits: the rinsing machine nozzles must be centered and the water pressure must be ≥1.5 and ≤2 bar.	Nozzles centering and water pressure ≥1, ≤2.5 bar.	The operators check at the start of the production and every 60 minutes the centering of the nozzles, visually, and the water pressure, reading the dedicated pressure gauge (calibrated). The results of the monitoring is recorded in the **MOD. 53**. All the operators performing the monitoring receive specific training once a year (see the training program and registry attached).	**1)** If, during the monitoring, a non-compliance is found, the operator stops the production line (following the **TAB. 7.5.06**). The Quality Control department, with the supervision of the PCQI, identifies and marks all the affected product (usually all the goods produced from the latest compliant check) with the **MOD. 08** and implements and records the Corrective Action by filling the **MOD. 07**, following the **PRO. 8.5.01**. The production line restarts only after the Corrective Action is implemented and approved by the QCM. **2)** If the NC is critical for Food Safety, all the goods produced from the latest compliant check are destroyed. The Food Safety Team, together with the Quality Control and Quality Assurance departments, reviews the rinsing procedure, the working parameters of the machine, the calibrations and its validation and, if necessary, modifies the procedure appropriately and perform a new validation. The Food Safety Team records its actions and verifications in the **MOD. 07** and performs a Root Cause Analysis, following the **PRO. 8.5.01**.	**1)** The laboratory technicians check daily that the operators perform the preventive control correctly and sign the **MOD. 53** for approval. The Quality Control department performs a documentary check weekly, signing the **MOD. 53** and, eventually, the **MOD. 07**, for approval. **2)** The Food Safety Team reviews the completed **MOD. 07** and verifies the efficacy of the Corrective Action/s implemented and the Root Cause Analysis, filling and signing the **MOD. 07** for approval, as described in the **PRO. 8.5.01**. The PCQI reviews the filled **MOD. 07** and signs it for approval within 7 days from its creation, as described in the **PRO. 8.5.01**. The position of the nozzles and the pressure of the water are calibrated and validated to remove hard plastic and glass fragments from the bottles, following the specific validation module (see attached). All the operators and technicians performing the monitoring receive specific training once a year (see the training program and registry attached). The PCQI reviews all the records within 7 working days from their creation.	**MOD. 53** **MOD. 07** **MOD. 08** **Validation Modules** **Training Program and Registry.**

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Process Preventive Control Step	Hazard(s)	Operating Limits / Critical Limits	Monitoring		Corrective Action	Verification	Records
			What	How / Frequency / Who			
17 Pasteurization	**Microbiological:** *Escherichia coli*, *Salmonella*.	Operating Limits: Target = 350 PU. Critical Limits: ≥150 PU, ≤ 900 PU.	The pasteurizer provides the correct PU.	A data logger is inserted in a sample bottle and runs through the pasteurizer measuring the inner temperature reached. A laboratory technician downloads the data collected and checks the Time/Temperature graph produced and the calculated PU achieved. The data logger is then placed back in a sample bottle for another run. This cycle is repeated continuously for each production run.	**1)** If, during the monitoring, a non-compliance is found, the QCM stops the production line (following the **TAB. 7.5.06**). The Quality Control department, with the supervision of the PCQI, identifies and marks all the affected product (usually all the goods produced from the latest compliant check) with the **MOD. 08** and implements and records the Corrective Action by filling the **MOD. 07**, following the **PRO. 8.5.01**. The production line restarts only after the Corrective Action is implemented and approved by the PCQI. **2)** If the NC is critical for Food Safety, all the goods produced from the latest compliant check are destroyed. The Food Safety Team, together with the Quality Control and Quality Assurance departments, reviews the preventive control, the working parameters of the machine, the calibrations and its validation and, if necessary, modifies the procedure appropriately and perform a new validation. The Food Safety Team records its actions and verifications in the **MOD. 07** and performs a Root Cause Analysis, following the **PRO. 8.5.01**.	**1)** The Quality Control department performs a documentary check weekly, signing the **MOD. 07**, for approval. **2)** The Food Safety Team reviews the completed **MOD. 07** and verifies the efficacy of the Corrective Action/s implemented and the Root Cause Analysis, filling and signing the **MOD. 07** for approval, as described in the **PRO. 8.5.01**. The PCQI reviews the filled **MOD. 07** and signs it for approval within 7 days from its creation, as described in the **PRO. 8.5.01**. The pasteurizer is calibrated and validated to achieve the correct PU, following the specific validation module (see attached). All the operators and technicians performing the monitoring receive specific training once a year (see the training program and registry attached). The PCQI reviews all the records within 7 working days from their creation.	**Data logger Time / Temperature charts with achieved PU value.** **MOD. 07** **MOD. 08** **Validation Modules** **Training Program and Registry.**

Sanitation Preventive Controls

NONE.

Food Allergen Preventive Controls

NONE.

Supply-Chain-Applied Preventive Controls Program

NONE.

Recall Plan

La Galvanina S.p.A. has an implemented Recall Plan (see attached full Recall Plan).

Annex 1 - Corrective Action Records

Corrective action records are maintained by the Food Safety Team Leader.
The Corrective Action Form below, or the **MOD. 07**, are to be completed whenever a non-compliance occurs. The **PRO. 8.5.01** describes in detail the steps to be taken to implement a corrective action.

Corrective Action Form	
Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Actions Taken to Restore Order to the Process:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date of Review:
Reviewed by PCQI:	Date of Review:

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Annex 2 - Food Safety Plan Reanalysis Report

The FSP as a whole must be reanalyzed at least every 3 years.

Checklist	**Date reviewed and initials of reviewer**	**Update needed Yes/No**	**Date Updated Completed:**	**Person Completing the Update** (initial or sign)
List of Food Safety Team				
List of products and processes in place at facility				
Product flow diagrams				
Hazard Analysis				
Sanitation Preventive Controls				
Food Allergen Preventive Controls				
Process Preventive Controls				
Supply-chain Preventive Control Program				
Recall Plan				

Bibliography

JØrgensen, K., 2005. Occurrence of ochratoxin A in commodities and processed food – A review of EU occurrence data. *Food Additives and Contaminants,* Volume 22, pp. 26-30.

LA GALVANINA S.P.A.

Recall Plan

La Galvanina S.p.A.'s Recall Plan outlines the activities that our company will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. La Galvanina S.p.A.'s recall plan shall be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change. The Plan will also be reviewed after any company recall.

Reviewed by PCQI Date: 28/05/2020

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This Recall Plan identifies information that is required for all sites owned by the company La Galvanina Spa.

Table of Contents

Introduction

The primary goal of a food recall is to protect public health by removing products from commerce that have been determined to be unsafe. A recall plan can aid in the execution of a recall by apportioning duties, centralizing current contact information, and providing prewritten templates for communications. Key Individuals that will be participating in a company recall should review the recall plan and be familiar with the execution of the plan.

Definitions

- **Class I Recall** – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II Recall** - A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III Recall** - A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- **Depth of Recall**: The level of product distribution for the recall (consumer, retail, institutional, wholesale).
- **Distribution List** - A product specific distribution list which identifies accounts that received the recalled product. Requested information includes type of business, account name, addresses, and contact information.
- **Market Withdrawal** - A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the regulatory agency or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- **Recall** - A firm's removal or correction of a marketed product that the regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- **Recall Team** – The group comprised of key staff with the expertise, authority, and responsibility to manage the recall.
- **Recall Plan** - A written contingency plan for use in initiating and implementing a recalling accordance with 21 CFR Sec. 7.40 through 7.49, 7.53, and 7.55. The Recall Plan should be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change.
- **Recall Strategy** - A planned specific course of action to be taken in conducting a specific recall, which addresses the depth and scope of recall, need for public warnings, and extent of effectiveness checks for the recall.

Recall Team

Assignment	Person	Contact Information
General Manager	Achille Marino	Office: (+39) 0541-751315 Email: achille.marino@galvanina.com
Sales & Marketing Alternate:	Andrea Pianini Samuela di Venanzio	Office: (+39) 0541-751315 Mobile: AP (+39) 3398715033; Email: andrea.pianini@galvanina.com samuela.divenanzio@galvanina.com
Research & Development Alternate:	Fiorenzo Guidi Matteo Biguzzi	Office: (+39) 0541-751315 Email fiorenzo.guidi@galvanina.com matteo.biguzzi@galvanina.com
Logistics	Federico De Angelis	Office: (+39) 0541-751315 Mobile: (+39) 3346792828 Email: federico.deangelis@galvanina.com
Shipping	Daniele Santolini	Office: (+39) 0541-751315 Email: daniele.santolini@galvanina.com
Quality Department Alternate: Alternate:	Matteo Matassoni Roberta De Stefano Lorenzo Valeriani	Office: (+39) 0541-751315 Email: matteo.matassoni@galvanina.com Email: roberta.destefano@galvanina.com Email: lorenzo.valeriani@galvanina.com
Administrative Support	Simona Paoli	Office: (+39) 0541-751315 Email: simona.paoli@galvanina.com
FDA Recall Coordinator	Cecilia M. Wolyniak	Office: 301-796-8209 Fax: 301-847-8635 orarecalloe@fda.hhs.gov https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

Recall Discovery Phase

The first step in a recall situation is the discovery of a potential product problem. Discovery can happen in many ways - lab discovery, employee observation, or through consumer complaints.
Lab discovery may occur by a product testing positive for a potential problem, such as high bacteria, improper pasteurization, or harmful chemicals being present. An employee observation could relate to parts of a filler being missing or broken glass being found in the filling area. Consumer complaints need to be divided into two classes: (a) routine complaints such as not enough CO_2, leaking package, and other non-critical issues, and (b) complaints that cause a health concern such as glass fragments in a product, contamination with allergens, or any other serious situations.

Determining if a Recall Action is Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe our product is causing illness	Assemble the recall team and ask Agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	**If no recall is needed**: Document why not and action.
News media story on problem with a type of food we produce	Assemble the recall team, review internal records		**If recall is needed**: • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble the recall team and review internal records		
Health Department believes our produce is causing illness	Assemble the recall team, contact appropriate regulatory agency		

Recall Decision Phase

Upon the discovery of a possible issue with a finished product, the following questions need to be answered:

Identity of the product in question.

1. What items are involved (includes products, brand names, and package sizes)?
2. What are dates of production and code dates of affected product?
3. At what location were the items produced (At the Galvanina Rimini Via Della Torretta plant, Val di Meti Apecchio plant, Galvanina Via Popilia plant, or from an outside vendor?)

Reason for the product to be of questionable quality.

1. What type of defect?
2. What is the cause of defect (if known)?
3. How was the problem discovered?

The potential health hazards.

1. Were any illnesses or injuries reported?
2. What hazards could result from the problem?
3. How severe is the problem to public health?

Quantity of the product in question.

1. Which production lines were affected and what shifts were involved?
2. How many of each affected item was produced?

What customers received this product?

1. Who received the largest? Identify from largest to smallest amounts.
2. Was distribution of the product restricted to certain areas or routes?

RECALLING FIRM Contacts

Provide this information to the FDA for clear communication:

Manufacturer name Rimini site: [LA GALVANINA S.p.A. – Via della Torretta, 2 - 47923 Rimini - ITALY]

Manufacturer name Apecchio site: [LA GALVANINA S.p.A. VAL DI METI. – Località Pian di Molino s.n.c. – 61042 Apecchio (PU) - ITALY]

Manufacturer name Rimini Via Popilia site: [LA GALVANINA S.p.A. VIA POPILIA. – Via Popilia, 97 - 47922 Rimini - ITALY]

Position	Name, Title	Contact Information
RECALL coordinator:	Andrea Pianini, Export Manager	Office: (+39) 0541-751315 Mobile: (+39) 3398715033 Fax: (+39) 0541-752110 Email: andrea.pianini@galvanina.com
Most responsible individual:	Massimo Ambrosini, Chief Executive Officer	Office: (+39) 0541-751315 Fax: (+39) 0541-752110 Email: massimo.ambrosini@galvanina.com
Public contact:	Samuela di Venanzio, Export Department	Office: (+39) 0541-751315 Mobile: (+39) 3484141639 Fax: (+39) 0541-752110 email: samuela.divenanzio@galvanina.com

Recall Submission to FDA / regulatory agency

The following information must be included in the recall submission:

1. PRODUCT INFORMATION:

- Product name (include brand name and generic name)
- Model, catalogue, or product order number(s)
- Product image
- Description of the product
    - Include if product is powder, liquid, tablet, capsule, etc.
    - Include the intended use or indications.
    - If the product is perishable, include the expected shelf life.
    - Include type of packaging (i.e. box, flexible plastic, glass).
    - **TWO COMPLETE SETS OF ALL labeling to your Local FDA District Recall Coordinator. Include**:
        - Product labeling (including ALL private labels)
        - Individual package label
        - Case label (photocopy acceptable)
        - Package Inserts
        - Directions for Use
        - Promotional Material (if applicable)

2. CODES (Production Identification Numbers):

- Lot/Unit Numbers
  (NOTE: If "all lots" are involved or the product is not coded, explain how non-recalled or reintroduced product may be distinguished from product subject to recall. Provide an explanation of your lot number coding system.)
- Expiration date(s) or Use by date(s) or Expected shelf life of product.
- Serial numbers (medical devices)
- UPC codes

3. RECALLING FIRM:

- Firm name, address, city, state, zip code
- Identify firm type (i.e. manufacturer, importer, broker, repacker, own-label distributor)

CONTACTS for Recalling Firm:

- Name/title/phone/fax number/e-mail address for RECALL contact
- Name/title/address/phone/fax number of the most responsible individual for the recalling firm
- Name/title/phone/fax number/e-mail address for public contact

4. MANUFACTURER:

- Firm name, address, city, state, zip code
- FDA registration number, if applicable

5. IDENTIFY FIRM RESPONSIBLE FOR THE VIOLATION/PROBLEM:

- Firm name, address, city, state, zip code

6. REASON FOR THE RECALL:

- Explain in detail how product is defective and/or violative.
- The date the firm made the decision to conduct a RECALL

- Explain how the defect affects the performance and safety of the product.
- If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.

- If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.
- If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. **Provide copies of any sample analysis**.
- If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).
- Explain how the problem occurred and the date(s) it occurred.
- Explain how the problem was discovered and the date discovered.
- Please explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.
- Explain why this problem affects only those products/lots subject to recall.
- Provide detailed information on complaints associated with the product/problem:
  - Date of complaint
  - Number of complaints
  - Description of complaint -include details of any injury or illness
  - Lot Number/Serial Number involved
- If a State agency is involved in this recall, identify Agency and contact.

REASON FOR THE RECALL:

Explain in detail how product is defective or violative	
The date the firm made the decision to conduct a RECALL	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, other), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications	

and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Number of complaints • Description of complaint -include details of any injury or illness • Lot Number involved	
If a State agency is involved in this recall, identify Agency and contact.	

7. HEALTH HAZARD ASSESSMENT:

- Provide your assessment of the health risk associated with the violation.
  NOTE: A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists are still in violation of the law and should be recalled.

8. VOLUME OF RECALLED PRODUCT:

- Total quantity produced
- Date(s) produced
- Quantity distributed
- Date(s) distributed
- Quantity on HOLD by Recalling firm and its distribution centers.
- Indicate how the product is being quarantined
- Estimate amount remaining in marketplace

  - distributor level
  - retail level
  - wholesale level
- Provide the status/disposition of marketed product, if known, (e.g. used, transfused, implanted, used in further manufacturing, or destroyed).

VOLUME OF RECALLED PRODUCT:

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • distributor level	
• customer level	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

9. DISTRIBUTION PATTERN:

- Number of DIRECT accounts (customers you sell directly to) by type, for example:
  - wholesalers/distributors
  - repackers
  - manufacturers
  - retail
  - users (medical devices - hospitals, clinics, laboratories)
  - consumers (internet or catalog sales)
  - federal government consignees
  - foreign consignees (specify whether they are wholesale distributors, retailers or users)
- Geographic areas of distribution, including foreign countries.
- **Provide a consignee list (names/address/city/state/contact name/phone number) to the local District Recall Coordinator. Be sure to include any**

foreign (including Canadian) customers and federal government consignees (USDA agencies, Veterans Affairs, Department of Defense)

- Indicate what the consignee list represents (i.e. all customers who were shipped recalled product; all customers who were *sold* recalled product; all customers who ***may have*** been shipped or sold recalled product because it was sold to them within the applicable time period.)
- Was product sold under a government contract? If yes, provide contract number, contract date and implementation date. If no, indicate so.
- Was product sold to any federal, state, or local agency involved in the *school lunch program*? If yes, list the consignees and provide quantity and sale and shipment date.

In addition, it is recommended that you notify both "ship to" and "bill to" customers of the recall so that:

- "Ship to" customers retrieve the product from their location.
- "Bill to" customers, if responsible, initiate the sub-recall.

DISTRIBUTION PATTERN:

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
▪ wholesalers/distributors	Example: *P&L Imports D.B.A. Resource Imports LLC* *Tel. 001 480 493 5301*

10. RECALL STRATEGY:

- Indicate the level in the distribution chain to which you are extending the recall. (i.e. wholesale/retail/pharmacy/medical user)
  If your recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to retail/pharmacy level.
- Indicate the scope of recall (i.e., which lots ae effected). Indicate the strategy for expanding the scope of the recall should additional lots be shown to be affected.
- Indicate the method of notification (i.e. mail, phone, facsimile, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.
- Indicate how letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)

- If initial notification is by phone, provide a copy of the phone script to FDA.
- If you have a web site, you should consider posting the recall notification on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)
- Report on what you have instructed customers to do with the recalled product.
- It is helpful for recalling firms to know the name and title of the Recall Contact for each of its consignees. Addressing a recall notification letter to a recall contact will expedite the recall process and reduce the potential for the notification letter to get misdirected.
- If product is to be returned, explain the mechanics of the process.
- Explain if this recall will create a market shortage that will impact on the consumer.
- Report on recall **effectiveness check** strategy. Include your actions for non-responders. See: https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
- Determine and provide your course of action for out-of-business distributors.
- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable CGMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.

Level in the distribution chain

Level	Included		Rationale if "No"
	Yes	No	
Wholesale/distributor	X		
Retail		X	We sell only to Wholesale/distributor

Instructions for Consignee Notification

The consignees will be notified by telephone and email.

The phone call will be recorded, and all the email exchanged with the client will be saved and stored.

In addition, we recommend that:

- You contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- The recalling firm and customers keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, (i.e. product relabeling), be performed by recalling firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For Drug Recalls: Misbranded drugs for re-labeling should be returned to the recalling firm.
- You contact your local District Recall Coordinator prior to release of reconditioned goods.

Product destruction/ reconditioning

La Galvanina S.p.A., as per its corporate policy, never performs product reconditioning or relabeling. In the event that it is necessary to destroy the product, this occurs according to the terms and conditions established with the customer. If the destruction is deemed necessary, it is performed in the USA and the importer is responsible for its fulfillment, La Galvanina S.p.A. pays all the associated costs.

CONSIGNEE LIST

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

Commercial customers

Name	*Street Address*	*City*	*State*	*Recall contact name*	*Contact phone number*	*Recalled product **was** shipped?*	*Recalled product **was** sold?*	*Recalled product **may have** been shipped or sold*
EXAMPLE: *P&L Imports D.B.A. Resource Imports LLC*	*10051 E Dynamite BLVD Suite G-160*	*Scottsdale*	*AZ 85262*	*Chris Mohrweis*	*(001) 480 493 5301*			

Evaluation of the Recall

Effectiveness Checks

La Galvanina S.p.A is responsible for determining whether the recall is effective. We will verify that all customers have received notification and that they have taken appropriate action. We will confirm receipt of the Notice of Recall with all accounts.

1. EFFECTIVENESS OF THE RECALL:

   It is the recalling firm's responsibility to assure that the recall is effective. Therefore, we recommend that you consider effectiveness checks for every recall. The purpose of an effectiveness check is to verify your recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain.

   The effectiveness check is your means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then you should take necessary steps to make the recall effective. These steps may involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

   Your District Recall Coordinator will provide a copy of a FDA document, "Methods for Conducting Recall Effectiveness Checks."

   Note: In addition to the effectiveness checks conducted by recalling firms, FDA may also contact a percentage of your customers (referred to as audit checks) as a means of assuring the recalling firm and its consignees are carrying out their recall responsibilities. If FDA's audit checks determine the recall to be *ineffective*, the recalling firm (or sub recalling firm if such is the case) will then be asked by FDA to take appropriate actions, including re-issuing recall notifications.

2. RECALL STATUS REPORTS:

   You will be asked to provide Recall Status Reports after initiating a recall (usually on a monthly basis but more frequently when indicated) to your local District Recall Coordinator. The reports requested will usually include the following information:

   - Dates and methods of customers notification
   - Number of customers notified
   - Number of customers responding
   - Quantity of RECALLED product returned or accounted for

- Number of customers that did not respond
- Estimated time frame for completion for recall
- Details of your recall effectiveness checks

3. ROOT CAUSE OF THE PROBLEM THAT RESULTED IN THE RECALL:

   We recommend that you provide this information to your local District Recall Coordinator once the root cause has been established. It is important to establish the root cause of the problem so that appropriate preventative measures can be taken.

4. CORRECTIVE ACTIONS TO PREVENT FUTURE OCCURRENCES OF THE PROBLEM:

   We recommend that you explain the corrective actions planned or underway that will prevent a similar problem from occurring. We further recommend that you provide this information to your local District Recall Coordinator when it has been established.

5. TERMINATION OF THE RECALL:

   We recommend that you evaluate your recall for termination when all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. A final status report and documentation of recalled product disposition should be provided to your local District Recall Coordinator before FDA will consider formal termination of the recall action. See: https://www.ecfr.gov/cgi-bin/text-idx?SID=0c9b377468fa18cb95af2580e018bb81&mc=true&node=se21.1.7_155&rgn=div8

   Note: Upon receipt of necessary termination information, the district's recall coordinator will prepare a recall termination document for Center and/or district management concurrence. When concurrence is obtained, the district office will notify the recalling firm that FDA considers the recall terminated.

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Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date of response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		
EXAMPLE: *P&L Imports D.B.A. Resource Imports LLC*	*Chris Mohrweis*	*Phone: (001) 480 493 5301*							

Template for Effectiveness Checks

https://www.fda.gov/media/79098/download (Effectiveness Checks Letter)

https://www.fda.gov/media/79117/download (Effectiveness Checks Response Format)

https://www.fda.gov/media/79131/download (Effectiveness Checks Questionnaire)

Customer Name and Address

Recall Effectiveness

LA GALVANINA S.P.A. PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THE RECALL NOTIFICATION BEFORE ANSWERING.

DATE: _____

1. Did your firm receive notification that La Galvanina S.p.A. is recalling its "Product Brand X" "Product Name X" product?
   YES NO

2. Did your firm receive shipments of the product being recalled? (If no, please sign and return).
   YES NO

3. Do you now have any of the recalled product on hand? (Please check inventories before answering).
   YES NO

4. If the answer to question 3 is YES, do you intend to return the product to La Galvanina S.p.A. as requested?
   YES NO

   If the answer to question 4 is NO, please explain your intentions:

_____

5. Have you received any reports of illness or injury that might be related to this product?
   YES NO

   If yes, please provide details: _____

_____

Name of person completing questionnaire: _____

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Title: _____

Return this form to: _____

Questions? Please contact La Galvanina S.p.A. at: (+39) 0541-751315, Mobile: (+39) 3398715033 Andrea Pianini (Monday to Sunday 8:30 a.m. to 8:30 p.m.) or via email: andrea.pianini@galvanina.com.

Effectiveness check summary

To be provided to FDA in case of recall

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

ANNEX

DRAFT Recall Notice

https://www.fda.gov/media/79108/download (Recall Letter)

https://www.fda.gov/media/79122/download (Recall Return Response)

La Galvanina S.p.A. Voluntarily Recalls [EXAMPLE: "Product Brand X" "Product Name X"] Representing [X quantity]
[--No Other Products Affected--]

Contact
Andrea Pianini,
Export Manager
Office: (+39) 0541-751315
Mobile: (+39) 3398715033
Fax: (+39) 0541-752110
Email: andrea.pianini@galvanina.com

FOR IMMEDIATE RELEASE – [date] – LA GALVANINA S.p.A. is voluntarily recalling [X] Lot Codes of EXAMPLE: "Product Brand X" "Product Name X", representing [insert quantity]. [Insert reason for recall].

See enclosed product label **<**for ease in identifying the product at retail/user level**>.**

This recall has been initiated due to <problem>. Use of <or consumption of> this product may <include any potential health hazard>.

We began shipping this product on <date> (or). This product was shipped to you on <date>. (If possible, provide consignee with shipping dates and quantities shipped.)

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Customers are advised to (e.g. destroy, return, hold for pick up). If you re-label, re-pack, or use the recalled products to produce new products, please contact the "FDA or State Recall Coordinator in your state".

This recall should be carried out to the <wholesale>, <retail>, <consumer> level.

Your assistance is appreciated and necessary to prevent <i.e. consumer illness or patient harm>. Please complete and return the enclosed response form as soon as possible. If you have any questions, call <name and telephone number>.

This recall is being made with the knowledge of the Washington State Department of Agriculture and <the Federal Food and Drug Administration> (if applicable). **This action relates <only> to EXAMPLE: <"La Galvanina S.p.A. / Client Company Name"> products with any of these Lot Codes printed on the package:**

- **[insert lot codes]**

No other Lot Codes, or any other <"La Galvanina S.p.A. / Client Company Name"> products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
"La Galvanina S.p.A. / Client Company Name" "Product Brand X" "Product Name X"	[insert product codes(s)]	92622015

La Galvanina S.p.A. is conducting this voluntary recall because EXAMPLE: "Product Brand X" "Product Name X"... "We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution".

For more information or assistance, please contact us at (+39) 0541-751315 Mobile: (+39) 3398715033 Andrea Pianini (Monday to Sunday 8:30 a.m. to 8:30 p.m.) or via email: andrea.pianini@galvanina.com

Template for Press Release

https://www.fda.gov/safety/industry-guidance/allergens-model-press-release (Allergens)

https://www.fda.gov/safety/industry-guidance/listeria-monocytogenes-model-press-release (ListeriaM)

https://www.fda.gov/safety/industry-guidance/c-botulinim-model-press-release (Clostridium B.)

https://www.fda.gov/safety/industry-guidance/salmonella-model-press-release-all-serotypes (Salmonella)

https://www.fda.gov/safety/industry-guidance/e-coli-0157h7-model-press-release (E.Coli)

LA GALVANINA S.P.A.
Via della Torretta, 2
47923 Rimini (Italy)

FOR IMMEDIATE RELEASE <TODAY'S DATE>

<COMPANY OFFICIAL NAME, TITLE, PHONE>

<DESCRIPTIVE TITLE OF RECALL>

<DATE><CITY> La Galvanina S.p.A, Via della Torretta, 2, Rimini, is recalling its "Product Brand X" "Product Name X" because they<SPECIFIC REASON FOR RECALL>.INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION

The recalled "Product Brand X" "Product Name X" was distributed <DISTRIBUTION DESCRIPTION>.

<SPECIFIC PRODUCT DESCRIPTION>

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME or OTHER> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact
<THE COMPANY and COMPANY CONTACT NUMBER> <TIME PERIOD>

Template for Food Safety Notice

Date issued:

FOOD SAFETY NOTICE

LA GALVANINA S.P.A.

<Descriptive Title of Recall>

<**CITY**> <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they <SPECIFIC REASON FOR RECALL>.INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>.

<SPECIFIC PRODUCT DESCRIPTION>

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME or OTHER> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact
<THE COMPANY and COMPANY CONTACT NUMBER>.

<INSERT PICTURE/LABEL of RECALLED PRODUCT>

Date Expires:

ORA Recall Coordinators

https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators (Ora Recall Coordinators)

ORA Recall Coordinators FDA (Only for USA)

Product Type	Division	Firm's State	Recall Coordinator
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East I	CT; MA; ME; NH; NY; RI; VT	**Christian Parra** Contact 158-15 Liberty Ave, 4th Floor Jamaica, NY 11433 Phone: 781-662-5475 orahafeast1recalls@fda.hhs.gov Pamela Ogonowski Contact One Montvale Avenue, 4th Floor Stoneham, MA 02180 Phone: 781-587-7449 Fax: 781-587-7556 orahafeast1recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East II	DC; DE; MD; NJ; PA; VA; WV	**Ruark Lanham** Contact 900 US Customhouse, Suite 904 200 Chestnut Street Philadelphia, PA 19106 Phone: 215-717-3738 Fax: 215-517-6649 orahafeast2recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East III	GA; NC; SC	**Emma Nesbit** Contact 60 Eighth Street, NE Atlanta, GA 30309 Phone: 404-253-1224 Fax: 404-253-1201 orahafeast3recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East IV	FL; PR; US Virgin Islands	**Wanda J. Torres** Contact 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 Phone: 787-729-8709 Fax: 787-729-8826 orahafeast4recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East V	AL; KY; LA; MS; OH; TN	**Krista Whitten** Contact 404 BNA Drive Building 200, Suite 500 Nashville, TN 37217 Phone: 615-366-7842 Fax: 615-366-7848 orahafeast5recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations East VI	IL; IN; MI	**Michael Larson** Contact 300 River Place, Suite 5900 Detroit, MI 48207 Phone: 313-393-8118 Fax: 313-393-8139 orahafeast6recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West I	MN; ND; SD; WI	**Kristine Zuroski** Contact 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 Phone: 612-758-7120 Fax: 612-334-4134 orahafwest1recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West II	IA; KS; MO; NE	**Matthew Sleeter** Contact 8050 Marshall Drive Suite 205 Lenexa, KS 66214 Phone: 913-495-5151 Fax: 913-495-5105 orahafwest2recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West III	AR; OK; TX	**Casey Hamblin** Contact 4040 N. Central Expressway Suite 300 Dallas, TX 75204 Phone: 214-253-5222 Fax: 214-253-5314 orahafwest3recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West IV	AZ; CO; NM; UT; WY	**Caroline Le** Contact Building 20, Denver Federal Center 6th Avenue & Kipling Street PO Box 25087 Denver, CO 80225-0087 Phone: 303-236-3045 Fax: 303-236-3551 orahafwest4recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West V	CA; HI; NV	**Marjorie Schultz** Contact 1431 Harbor Bay Parkway Alameda, CA 94502 Phone: 510-337-6898 Fax: 510-337-6705 orahafwest5recalls@fda.hhs.gov
Human and Animal Food & Cosmetics	Division of Human and Animal Food Operations West VI	AK; ID; MT; OR; WA	**Ahn Trinh Nguyen** Contact 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 Phone: 425-302-0467 Fax: 425-302-0403 orahafwest6recalls@fda.hhs.gov

Good Manufacturing Practices (GMP)

DEVELOPED BY:

“LA GALVANINA S.P.A.”

For

GALVANINA PLANT

Via della Torretta, 2 - 47923 Rimini (RN)

C.F./P.I. 00142010404

TEL: (+39) 0541 751315 – FAX: 0541 752110

galvanina@galvanina.com - WWW. galvanina.com

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DISTRIBUITO A _____ IN DATA _____

0	**21/05/2019**		
REV.	**DATA**	**ELABORAZIONE / VERIFICA R.A.Q.**	**APPROVATO PCQI**

INDEX

Claudio Innocenti

Introduction

INTRODUCTION	The GMPs must be understood as standards in continuous evolution and improvement, based on the experiences of the plant, changes to environments, plants and products, changes in the guidelines made by the Quality Department of La Galvanina S.p.A. or changes in the current legislation. Good manufacturing practices are an integral part of an integrated approach to quality and safety risks. The elements of the GMPs represent prerequisites (PRP) identified by HACCP as necessary to maintain a hygienic environment throughout the production and distribution chain. Periodically the prerequisite program is subject to verification through the application of a surveillance plan.
PURPOSE AND FIELD OF APPLICATION	The purpose of this manual is to define the essential principles of the GMP applicable to the Galvanina plant in Rimini (RN).
DEFINITIONS	For the purposes of this document, the definitions given CFR Title 21 Part 117 Subpart B - Current Good Manufacturing Practice, apply.
REFERENCES	For the purposes of this document, the references listed in the management system manuals apply.

1. 117.10 Personnel

The correct behavior of the staff, both from a hygienic and professional standpoint, is the basis for guaranteeing the quality of the products. These rules are indicated in the company internal regulations (**PRO. 5.6.01**, **IST. 7.5.00 B**, **Politica Aziendale**). Higher attention is required if the staff works in the filling areas.

The personnel is periodically trained, informed and involved to increase their understanding of the GMPs and the importance of their implementation. It is the responsibility of the factory managers to provide adequate information for their personnel to observe and apply all the rules indicated (**IST. 7.5.00 B**).

a) Disease control

All the staff working close to the production lines follows at least a 2-hour internal training course annually on GMPs and GHPs. They are instructed to report to their supervisors if they have or think to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination. If there is a possibility of food, food-contact surfaces, or food-packaging materials to become contaminated, the employee presenting the illness is excluded from any operations which may be expected to result in such contamination, until the condition is corrected. If conditions such as open lesions, boils, and infected wounds are adequately covered, the employee can be permitted back to the production areas.

All the Galvanina personnel are required to undergo yearly medical checkups with the factory doctor.

The health checks are performed by a specialist in Occupational Medicine as consultant for the Galvanina plant, in the manners and in accordance to the deadlines established by the current legislation.

Every individual who carries out activities within the Galvanina plant must, in any case, take care of his own and others' health and safety, as instructed, in accordance to the current legislation.

b) Cleanliness

The behavioral and hygienic rules are communicated to the operators by referring to specific procedures and operating instructions (**IST. 7.5.00 B**).

Training and updating the personnel is fundamental for the correct application of the instructions and therefore it is expected to undergo, on a regular basis, general and specific courses on hygiene, GMPs, CCPs and Quality management for each activity carried out:

. production (bottling machine operation);

. maintenance (intervention methods in protected areas);

. sanitization (intervention methods, plant updates and specific products);

. logistics (hygienic aspects related to warehouses, trucking, handling).

1) The Galvanina staff must wear the clothing, provided by the company, required to carry out the tasks assigned.

It is a general rule that the change of clothing takes place exclusively within the factory, in the dedicated locker room.

The company annually supplies to the personnel two complete sets of clothing so to allow the alternated washing, to ensure that the clothes worn are suitably clean to carry out the activities in the food company.

The hygienic suitability of the work clothes is verified during internal inspections. The clothing is specific depending on the department.

It is not allowed to wear additional clothing (knits, jackets, etc.) over the indicated clothing. In the event of access or interventions in areas that are not heated during the cold season, the use of a padded jacket is allowed.

2) The behavioural rules required to all the operators are described in the **IST. 7.5.00**.

In case of sneezing and coughing, it is required to use disposable tissues that after use must be thrown into the waste containers.

In case of wounds on hands, arms, face, even if small and superficial, they must be completely covered with suitable bandages to guarantee absolute isolation from the external environment.

The use of perfume, aftershave or particularly odorous toiletries must be moderate.

It is required to keep the hair, beard and nails clean and tidy (without enamel).

The observance of the behavioral and hygienic rules, indicated above, is also required to the external personnel, in charge of carrying out activities within the establishment, and to guests and visitors.

3) The hands and forearms must be washed several times during the work shift with soap under a jet of hot water operated by an automatic command. Hands must be well dried with electric hand dryers and sanitized afterwards with an alcoholic solution containing chlorhexidine.

In all the toilets, soap and sanitizer dispensers are installed to be always used before returning to the production lines.

It is necessary to wash and disinfect the hands before entering the bottling premises, after having used the toilets, after each work stoppage, after having covered the nose or mouth because of sneezing or coughing, after having, for example, moved machinery from the bottling environment to another, after moving the waste containers.

4) It is required that the personnel working in the departments of the plant remove, for reasons of safety and hygiene in the workplace, all visible personal objects (rings, earrings, bracelets, watches, piercings, etc.) with the sole exception of the wedding ring. The glasses must be secured so that they do not fall.

5) Gloves are not required as the food products are never touched by the operators or openly exposed to the environment.

6) All personnel working in areas where vision and hearing could be in danger are provided with adequate protective equipment. In case of special operations it is necessary to wear the specific equipment P.P.E.

The use of the headgear is mandatory when entering the filling areas and required in all other areas for the operating personnel. In case of direct contact with the primary packaging material (bottles and caps) and / or filling systems, clean disposable gloves, mask and overshoes must be worn.

In case of breakage of the disposable equipment during the activities these must be immediately replaced.

7) Lockers and toilets, built in accordance with the current legislation, are available in the plant to all the staff. The maintenance of these premises is the responsibility of the external company that provides the cleaning service. The staff of the Galvanina plant, in any case, is obliged to keep the changing rooms in order, not to leave objects outside the appropriate lockers, to use the double compartment of the lockers correctly by storing work clothes separately from civilian clothes.

8) The intake of loose food and beverages is prohibited in the entire area of the plant with the exception of small packaged snacks and pet water made available by the company, which must be consumed in the dedicated area. There is also a no-smoking policy throughout the plant area.

If during the production cycle empty bottles fall to the ground they must be discarded. The lip and rim of the bottles must never be touched with hands unless covered by sterile disposable gloves.

It is the responsibility of the Quality Control department and Production Manager to verify the compliance and the correct application of the company procedures.

9) The personnel accessing or working in the filling area and syrup room must wear a clean, disposable coat over the regular working clothes, a hairnet and, eventually, a beard cover (IST. 6.2.01). To prevent any contamination all the personnel are trained at least once a year to follow the cGMP instructions described in the **IST. 7.5.00 B.**

2. 117.20 Plant and grounds

a) Grounds

1) The plant operators and cleaning personnel are trained and updated yearly on the cGMPs. The cleaning operators record their actions daily in the **MOD. 12**. The management of order and cleaning is the responsibility of Production and QC.

The green areas surrounding the buildings do not present relevant risks for the bottling phases of mineral water and / or soft drinks.

The Cleaning operations are described in detail in the **IST. 7.5.28 A**.

2) - **3)** The food processed by La Galvanina S.p.A. (Mineral Water, Flavored Water) is never exposed to the environment, always running inside stainless-steel pipes and tanks.

The buildings and external areas maintenance works are assigned to external companies and checked regularly by the Quality Control technicians, recording the findings in the **MOD.335**.

4) The Galvanina plant is equipped with a liquid waste treatment system. The treated liquid wastes are then discarded in the public sewage. All the wastes are managed following the **PRO.05** Wastes Management.

5) The environment surrounding the plant grounds has been analyzed and attention has been directed towards the pest control plan, which is managed by and external qualified and certified company and checked regularly by the Quality Control operators.

b) Plant construction and design.

The site consists of the following main structures:

- Offices: administration;
- Laboratory;
- Toilet and changing rooms;
- Factory;

• Warehouse.

2) All bottling departments comply with the following provisions:

. They are separated from non-productive environments by walls and glass; communicability is allowed through doors equipped with a return spring. These doors remain closed during production.

. The final packaging phases (boxing, cartoning, palletizing and pallet wrapping) take place in rooms separated from the remaining part of the bottling lines;

. They have a washable floor and have a sufficient slope for the spontaneous flow of fluids towards the evacuation drains;

. The departments are equipped with an autonomous drainage network, collected on the floor with siphon drains (holding bell under the grilled cover) built entirely in stainless steel;

. The edges against the walls are rounded to avoid the accumulation of dirt and to facilitate cleaning;

. The walls are covered up to 2 meters from the floor with washable and sanitizable clinker tiles;

. Near the lines there is a stainless steel sink with pedal-operated ignition for cleaning hands and forearms;

. They are equipped with insect screens on the windows.

The filling area is equipped with a controlled filter suction system. All the buildings in question have been designed and built in compliance with the relevant regulations.

3)-4) Raw materials and finished products are stored in warehouses owned by La Galvanina S.p.A. The following warehouses and stores can be listed:

. temporary warehouse adjacent to the packaging;

. raw materials cold room (+ 5° C / -18 ° C);

. external warehouse for food raw materials, packaging and finished product;

. chemicals warehouse;

. external warehouse for labels and packaging.

All warehouses comply with the following:

. they are separated from the productive environments;

. they are sufficiently spacious to allow the correct storage of the materials and products for which they are intended;

. they are equipped with the appropriate structures and systems to allow the correct storage, preservation and transport of the materials and products for which they are intended;

. they are easy to clean;

. they are equipped with structures that allow them to be closed towards the outside.

The purchase and installation of new plants is evaluated not only on a technical basis but also on a qualitative basis.

In the case of new plants, an interdisciplinary working group is assembled, able to evaluate all the plant aspects regarding the productivity, maintenance, safety and assesses the risks from a hygienic / sanitary point of view according to the principles of HACCP and HAPRC.

5) The lighting provided is adequate and compliant with the current regulations. The light bulbs are shatter resistant and regularly checked by the Quality Control technicians (see **MOD. 185** and **MOD. 185B**).

6) No allergens are processed or introduced in the production plant. The ventilation systems are adequate and checked regularly by the operators assigned to maintenance (see **TAB. 6.3.01** Maintenance Program).

7) The bottling and syrup room areas are equipped with insect screens on the windows. The external doors are equipped with brushed at the bottom to prevent the entrance of pests. Pest traps compliant with the current regulations are placed on the ground and on the walls.

3. 117.35 Sanitary operations

a) General maintenance

The maintenance of the buildings is managed by the Maintenance Manager (MM) and any external consultants. These works are generally entrusted to qualified external companies that, before entering the company, are instructed in the hygiene and health and safety regulations in force within our factory.

The maintenance of the buildings aims to maintain them well over time, but also to update them and improve sanitary conditions. Maintenance is provided by the General Management and the Plant Management in the annual budgets and possibly in the investment plan.

Any maintenance carried out by the Galvanina personnel or external companies must follow precise instructions in order to safeguard the safety of the product.

The maintenance personnel must be appropriately trained in regards of the hygiene aspect and the risks of pollution that may occur during the operating phases.

The work done by external companies must be supervised by a factory manager who must prevent and check for the presence of:

. powders;

. odors of oils, paints;

. exhalations of machines, engines;

. as already indicated for stable maintenance.

Once the work is completed, before start-up, the area must be cleared up and must be reviewed by a work group consisting of Quality Assurance, Maintenance and Production, that creates a start-up report after maintenance, indicating the activities carried out and the controls performed at the start of the plant.

The operations of maintenance, renovation or construction of new plants / buildings can have an impact on the quality of the product and are first evaluated by the Quality Assurance department to identify all the risks of contamination, planning in advance the most suitable operating conditions for the proposed activities.

If major repairs or modifications are made, the area where the work is carried out must be separated appropriatly from the other process areas and the production activity must be stopped if necessary.

The integrity of the floors, walls and ceilings of all rooms, especially bottling departments, must be kept under constant control. Broken or damaged tiles must be replaced. Cracks or holes in walls must be repaired.

The maintenance plans follow a schedule approved by the Plant Management. These plans take into account the normal wear and tear factors due to use, allowing to prevent the emergence of serious problems during the filling phases such as the contamination with the micro-parts of the system (gaskets, screws, etc.).

The maintenance plans are distributed to all the services concerned.

The timing of post-intervention cleaning and sanitization plans is also considered when evaluating the interventions.

When the line restarts, the Quality Control will take some additional samples in order to verify the suitability of the product.

Spare parts that come into contact with the filling and adduction network must always be cleaned and sanitized before assembly.

b) Substances used in cleaning and sanitizing; storage of toxic materials.

1) The management of chemical products, regarding the receipt and handling to the production departments, is the responsibility of the Logistics department, assisted by QC (Quality Control).

The following indications are mandatory:

. all the chemical products used must be approved by the Quality Control Manager;

. all chemical products must be contained in suitable, properly labeled containers;

. mineral water bottles or glass / PET drinks bottles must not be used to contain chemicals and / or lubricants and greases;

. always read carefully the labels of the chemical products before using them;

. never mix chemical products (to avoid exothermic reactions with formation of splashes and / or toxic substances);

. the methods of use of the chemical products defined by the Quality Control must always be respected;

. always wear the individual protection devices (gloves, glasses, masks, coats) during the use and handling of chemical products;

. never leave chemical products around the production departments and warehouses. At the end of the cleaning and sanitizing operations these must always be collected and returned to the appropriate storage areas;

. in the production departments there must be only the products necessary for their functioning and cleaning tools dedicated exclusively to the designated area.

A copy of the technical and safety data sheets of all approved chemical products are in possession of Quality Assurance. A copy is kept near the storage of chemicals.

Chemical products warehouse

Inside this warehouse the chemical products used for sanitizing are stored in special containment tanks and divided as follows:

. acid products;

. basic products.

The storage must be differentiated by product type, arrival date and guarantee the management F.I.F.O. of stocks.

A copy of the technical and safety data sheets of all approved chemical products are in possession of Quality Assurance. A copy is always kept near the storage of chemicals.

To prevent the deterioration of the active ingredients contained in chemical products, they are kept away from sunlight and direct heat sources and in well-closed and identifiable packs. Storage facilities, equipped with specific containment tanks, are clearly identified and are located in external factory areas, closed and managed by authorized personnel.

For any product used, whether detergent or disinfectant, careful consideration is given to the instructions provided on the package with regard to dilution methods (mixing of product with water), contact times with surfaces, and the use of any necessary safety equipment (protective glasses, mask and gloves). Dilution proportions are specified in the various operative instructions for cleaning.

Different products are never mixed together, unless in accordance with the instructions for use indicated on the label. In general, acid and descaling products are used in the production areas, given that machines are made completely in steel. For all other machines, instead, basic or neutral products are used. Chemical cleaning products must be used in accordance with the instructions given by the supplier, and are stored in well-identified areas assigned for this purpose inside the factory (see location plans).

The operatives of the specialized external company dilute the products needed for cleaning activities. Every container used to dilute chemical products used for cleaning is correctly identified and is used only for that specific purpose.

All cleaning operatives are trained by technicians of the company which supplies the chemical products, defining the methods of use of the products and any associated risks.

2) Additional instructions on how to manage toxic chemicals are present in the **PRO. P-4.4-5**.

c) Pest control

In order to avoid problems related to the presence of pests, the Galvanina plant carries out a program to control and reduce them.

Pest prevention and control activities (creeping insects, rodents) are carried out by a specialized external company, under the supervision of the Quality Control Manager. The activities of prevention and control of flying insects are carried out by the QC department under the supervision of the Quality Control Manager.

The contract stipulated with the external pest management company defines:

. the number of annual interventions to be carried out (deratization and disinfestation);

. a general timetable for carrying out the interventions;

. the type of products used;

. the use of a mapping of the baits and of the areas subjected to treatment;

. the responsibilities;

. the methods of conducting rodent control activities;

. any corrective actions taken when necessary;

. the activity registration forms (intervention reports);

. the economic aspects.

All the activities carried out by the staff of the external company are controlled and supervised by Quality Control.

A significant monitoring system was implemented, with prior analysis of pest types and identification of the areas most at risk.

The analysis was conducted by means of inspections extended to the entire plant, with further observations of the surrounding watercourses, rainwater drainage and stagnation areas.

During the inspections, particular attention was paid to detecting shortcomings that could potentially lead to infestations, for example structural and / or architectural deficiencies, waste management, raw materials storage and packaging methods, wastewater drains, departments hygiene, environmental microclimate .

Following the inspection activity, the pest monitoring and control system was structured and started up, positioning baits in the points deemed critical.

In particular, the system is structured as follows:

. Control and capture of flying insects (flies - mosquitoes - Lepidoptera - Hymenoptera).

The intervention is carried out by placing, in certain points of the building, special insecticide lamps compliant with EEC Directives 89/336 and 93/68 and provided with CE marking. The lamps are controlled and maintained by the QC and Maintenance departments.

. Control of walking and crawling insects (ants - spiders - cockroaches).

The control is carried out by placing special pheromone traps along the internal walls of some departments and warehouses, in relation to the types of insects present in the monitored areas. Moreover, periodically, misting treatments are performed with a pyrethroid insecticide.

. Rodent control (Mus Musculus - Rattus Rattus - Rattus Norvegicus).

At the points identified, ratticide bait dispensers are positioned in all the internal and external areas of the building except for the productive areas. Particular attention is paid to the protection of entry routes.

Every month (12 annual checks) the specialized company providing the disinfestation service checks all the numbered and indicated stations (special dispensers) on the plan, recording, on an intervention report issued to the plant, the type of pest and the number of specimens found.

In addition, exhausted baits are restored, periodically changing the active ingredients and attractive substances. The active ingredients used for the formulation of the starchy baits exert an anticoagulant action and a single ingestion of a few grams of bait is enough to bring the rodents to death after 4 - 5 days.

All the operations described are supported by a plan of the building, agreed between the Parties, showing the complete mapping of the applied monitoring system, on which the points where the baits, their type and insecticide lamps are located can be easily identified. All the baits are indicated by a sign reporting the content, the number and the antidote to be used in case of ingestion.

The work program described is integrated with basic prevention interventions, consisting of:

. planned deratting operations, already activated during the monitoring phase;

. scheduled disinfestation and disinfection operations in the highest risk periods;

. use in an integrated way of all the tools useful for carrying out a safe disinfestation and with the least possible environmental impact;

. removal of possible sources of infestation, collecting the waste in the appropriate containers, emptying these regularly, keeping the internal and external areas clean and tidy, keeping the doors and gates that lead to the outside closed, applying insect screens to the windows ;

. all operators are aware of the fact that baits must never be touched, both for safety and for the effective maintenance of the monitoring system;

. operators must also report any pest sightings and respect the baits, reporting any damage to them.

In the event of an infestation in progress, we will intervene with:

. increase in the number and type of specific baits for the type of pest;

. targeted fight, through the use of chemical substances, compatible with food production activities, to fight the infestation at the root (for example the fight against ants in outdoor spaces when the eggs hatch).

In this way, it is possible to correct the infestation before it can extend to less controllable surfaces.

In all cases the corrective actions always depend on the type of infestation in progress, therefore each intervention requires evaluations and consequent decisions to be taken.

d) Sanitation of food-contact surfaces. e) Sanitation of non-food-contact surfaces

1) – 2) Internal circuits and food contact surfaces are subject to daily sanitization by specialized and trained operators. Programs are prepared in which the methods of carrying out sanitation (times, temperatures, products, and concentrations) are defined.
The sanitation procedures, the verification of effectiveness and the recording modules are described in the **PRO. 7.5.07** (see attached). The CIP sanitization procedures for the deaerator/saturator and filler are described in detail in the **IST 7.5.03**.
The effectiveness of cleaning and sanitization operations is verified by the quality control technician, who takes surface swabs as envisaged by **TAB. 7.5.06** "Plan of checks". Samples are taken at weekly intervals and are recorded on **MOD. 59** "Bioluminator Checks". Swabs are taken after cleaning and sanitization operations and subsequent rinsing operations. Effectiveness is assessed using a bioluminator, referring to biovalues expressed in RLU (Relative Light Units):

RLU BIOVALUE GUIDELINES:

Very clean surface < 200
Clean surface from 200 to 500
Dirty surface > 500
Samples must be taken on a surface area of about 100 cm² (10 cm x 10 cm). If the surface is found to be dirty (>500 RLU), the cleaning and sanitization operations must be repeated, followed by another swab test on the surface. In case of a trend of negative results, if the cause cannot be attributed to incorrectly performed procedures but to the ineffectiveness of the cleaning and sanitization program itself, the program must be appropriately reviewed and updated, noting the steps taken on the NON-CONFORMITIES form.
All registrations for cleaning and sanitization operations are collected and filed by the QCM. The results of checks on the effectiveness of cleaning operations are recorded on **MOD. 59** "Bioluminator Checks", which is used to compile annual statistics on **MOD. 59 B** "Bioluminator Statistics", allowing the trend in cleaning and sanitization operations to be monitored.

TAB. 7.5.05 shows the general programming of cleaning and sanitization activities performed in the factory. Sanitization operations for filling systems are planned weekly by the QCM and are recorded on **MOD. 212**. "Planning of Sanitization Operations".
The performance of these operations is registered by the operative who carried them out on the specific forms indicated by **TAB. 7.5.05**.

e) Sanitation of non-food-contact surfaces

A regular cleaning and sanitation plan is followed inside the factory and annexed warehouses. Cleaning and sanitation must be understood as an essential phase of the production process and as a basis for obtaining products of good hygienic-sanitary quality.

Cleaning and sanitation include:

. ordinary cleaning (offices, corridors, changing rooms, restaurant facilities, toilets) contracted out to an external company that uses products approved by QCD. The cleaning program carried out is an integral part of the contract;

. departments and warehouses cleaning, entrusted to the operators of each department, according to the needs and timing available or outsourced to an external company that uses products approved by QCD. The methods of execution (products, equipment, times, points to be cleaned) have been indicated by the Quality Control;

. sanitation: internal circuits and strategic food surfaces are subject to daily sanitization by specialized and educated operators. Programs are prepared in which the methods of carrying out sanitation (times, temperatures, products and concentrations) are defined;

Operatives in departments are responsible for keeping their department in suitable conditions of hygiene, and to remove bulky waste as soon as possible, such as:

- Packing materials in the syrup room;
- Packing materials in the labeling/case packing department;
- Non-conformant bottles and glass in the bottling department.

Cleaning operations for internal spaces are planned and defined in **MOD. 12** "Programming and Registration of Cleaning Operations" by the QCM, who verifies their effectiveness.

Cleaning operations performed by a specialized external company regard:

- Factory floors;
- Windows/glass panels;
- Ceilings and walls;
- Entrances (main and secondary doors);
- Offices, laboratory, changing rooms and toilettes;
- Warehouses for materials and finished products.

The following operative methods are used:

- Clean away glass and production residues from machines, conveyor belts, labelers, case packers and floors;

- Empty and wash the bottle washer tanks;
- Rinse machine surfaces and floors with water;
- Wash floors with single-brush cleaning machines using specific products;
- Always leave products to act for 15 minutes, then rinse with abundant water.

The products used for cleaning of the offices are supplied directly by the external company. In production spaces, only products approved by the QCM are used.

All cleaning operations are planned and recorded in **MOD. 12** "Programming and Registration of Cleaning Operations" and are checked in **MOD. 335** "Checklist for Cleaning of Spaces".

The equipment used by the external company is kept in closed storerooms.

f) Storage and handling of cleaned portable equipment and utensils.

The operatives of the specialized external company are responsible for the cleaning of equipment and for its storage, and must replace it when necessary.

Equipment for routine cleaning is managed by the operatives of the specialized external company in a dedicated area of the factory, well ventilated and with restricted access, where good hygiene conditions are maintained to guarantee the suitable conservation of the equipment. Cleaned equipment must be returned to this area after cleaning operations, avoiding contact with the floor.

In addition to the rules of good practice that all Galvanina personnel must comply with, maintenance operators must take extreme care when carrying out activities in areas considered to be at risk of contamination.

The use of equipment such as screwdrivers, pliers, etc. in case of contact with parts which are in contact with the food products, must be sanitized.

It is good practice for each bottling line to always have a minimum stock of spare parts, such as mouth seals, deflectors, straws and complete taps, sanitized and stored according to the correct practice.

Any sterilized and sanitized materials must remain wrapped in special plastic bags until they are replaced, and kept in the dedicated cabinets.

4. 117.37 Sanitary facilities and controls

a) Water supply

The Galvanina, with its natural mineral water sources "Galvanina" and "Fontesana", is located in the San Lorenzo Mount area - SW of Rimini on the Covignano hills at ca. 150 s.m., with the advantage of not having other industrial activities nearby. The company has been bottling the "Galvanina" mineral water since 1901, but it is known as the Ancient Roman Spring since it was already known in the 1st century B.C.

The water is caught from the spring and led, through pipes, into a sedimentation tank. The pipes and the tank are in stainless steel. The sedimentation tank is sealed with an unbreakable and tempered glass cover.

The mineral water, after the sedimentation tank, is brought to the plant by the force of gravity. The pipes are made of food-grade polyethylene all the way to the storage tanks at the plant. The spring is protected by a concrete construction, covered with steel and stone mosaic tiles.

The structures built for this purpose have adequate characteristics for the hygienic protection of the catchment and are such as to allow the necessary controls, cleaning operations and local ventilation.

The premises housing the collection works are equipped with building structures designed to guarantee the primary and secondary protection of each source and are kept constantly clean; access to such premises is permitted only to duly authorized personnel.

The entire catchment area is kept under continuous observation by the Company.

The ground water pipe is connected to the mineral water delivery pipe and to a pipe with a stainless steel tap to allow the sampling. A flow meter (type Endress Hauser) is fitted on the mineral water supply pipe as required by current legal provisions.

The joint welds of the individual tubes are made with the best available technologies, to avoid rough surfaces and possible corrosion principles.

The mineral water conveyed to the plant is temporarily stored in four impermeabilized reinforced concrete storage tanks. There are also three stainless steel storage tanks.

The mineral water falls inside the tanks, thus creating a solution of continuity with the feeding water pipe.

The tank allows the storage of water on weekends or during production pauses, guaranteeing greater bottling potential. The mineral water comes into contact with the surface of the tank (in stainless steel) and with the air present inside it, which is suitably filtered and forced into the tank itself.

This procedure guarantees a continuous slight over-pressure of the air inside the tank thus avoiding the accidental entrance of non-sterilized air from the external environment through the overflow pipe of the water. The entire circuit of mineral water, from collection to bottling plants is shown in appropriate updated diagrams and archived by the Technical Services.

The mineral water from the tanks is conveyed by falling into stainless steel pipes and transferred to the respective bottling lines. The surfaces of the collection, adduction and transport works, the pumps, the sampling taps, the valves and the gaskets of the accessories connected to the pipes and tanks are made of materials suitable for contact with food: STAINLESS STEEL 316L, VITON, EPDM, PTFE; the joints of the pipe heads are made entirely by TIG welding in an inert gas environment.

The drinking water used in the plant is supplied by the public mains.

The distribution lines of the drinking water network are completely separate from that of mineral water.

The osmotic water leaving the reverse osmosisproduction plant serves to feed the thermal power plant. The softened water dedicated to the CIPs is conveyed in a closed loop, from which the detachments that feed the CIPs of the various lines branch off.

The mains drinking water distribution systems are made with AISI 316 L stainless steel pipes.

The water quality is monitored in accordance with the current legislation.

The water used for the fire protection system is also drinkable.

Legionella: network water, both hot and cold, is monitored to prevent any risk of legionellosis, even if it does not represent a risk to food safety.

b) Plumbing

All the plumbing is of suitable size and design and is maintained in optimal working conditions.

1. There is the adequate quantity of water that derive from the Galvanina water source.
2. The sewage and liquid disposable is properly to convey waste from the plant.
3. The entry points of the pipes in the production area do not represent an easy access for the entry of dust or weeds and do not lead to the loss of overpressure.
4. The floors around and near the bottle washing and filling machines are provided with drainage channels. All the pipes carrying wastes are equipped with backflow preventer valves.
5. Pipes are not placed over open bottles, except those that bring the product to the filler. Each distribution system is identified.

c) Sewage disposal

The liquid residues, coming from the production cycles (bottle washing and sanitizing detergents) of the Galvanina plant, are conveyed to the company purifier, before delivering them to the body of surface water.

The Quality Control department is responsible for verifying the correctness of the discharges and verifying the proper functioning of the instruments.

The Production Manager is responsible for the proper functioning of the systems.

d) Toilet facilities

Toilet facilities, built in accordance with the current legislation, are available in the plant to all the staff. The maintenance of these premises is the responsibility of the external company that provides the cleaning service.

e) Hand-washing facilities

In all the toilets, sinks with warm water, soap and sanitizer dispensers are installed to be always used before returning to the production lines.

Sinks with warm water, soap and sanitizer dispensers are also placed proximity of the production lines.

f) Rubbish and offal disposal

Processing waste like bottles and caps must not be reused in any way for bottling.

Waste collection is carried out differently based on the waste production areas.

The aforementioned processing waste, if possible pressed into bales, is sent to authorized disposal companies.

Materials in contact with the product:

. crown caps and aluminum caps: they are collected separately in special containers for material recycling.

. plastic materials: they are collected separately in special containers for material recycling or disposal.

. paper and cardboard: they are collected separately in special containers for material recycling.

. glass: it is collected in special containers for material recycling.

The industrial waste collection bins are placed outside the production departments in specifically delimited areas.

The enclosed layout shows the waste flow in relation to the flow of the finished product, raw materials and personnel within the plant.

All the waste is handled with care in order to prevent the contamination of the product and the production.

Special waste (neutralizing sludge, oils, etc.) is collected in suitable containers and delivered to an authorized disposal company.

Waste from the microbiological laboratory: they are collected in special containers and sent to an authorized disposal company.

Urban waste is collected in black bags and deposited closed in bins placed outside of the plant by the staff performing the cleaning.

It is the duty of all operators to:

. use the appropriate waste collectors;

. keep these binders closed;

. do not dispose of waste of any kind around the plant;

. carry out the recycling according to the instructions given here.

Waste management is the responsibility of the Production Manager.

5. 117.40 Equipment and utensils

a) 1)-2) GMPs common to all production lines are the following:

. in bottling plants all parts in direct contact with the product (saturators, fillers, liquid transfer pipes, pumps, valves and all the gaskets used) are built with materials suitable for contact with food (AISI 316L stainless steel , EPDM, Viton, PTFE) and resistant to cleaning operations with detergents and sanitizers;

3)-4) all the machines are chosen with particular attention to their hygienic design (both for external cleaning and, possibly, for internal sanitation);

5) the state of the machines is constantly evaluated in order to guarantee the quality (hygienic-sanitary, appearance, legal requirements, etc.) of the finished product and maintain a technological level in compliance with current standards. The replacement of obsolete machines is scheduled by the General Management and the Plant Management in the investment plan;

. the line operators must carry out the monitoring and insert all the process controls relating to the station supervised by them in the specific forms. Monitoring (frequencies, methods, critical limits, registration documentation, responsibilities and corrective actions) are described in the QMS;

. it is the duty of every operator of any level to monitor the environment, the plants, the production in order to guarantee the quality of the finished product. It is the duty of each operator to warn his superior and Quality Control of any event that he believes may harm the quality of the products;

. it is the duty of each operator to keep his work area tidy and clean.

. Compressed air is filtered to prevent any risk of product contamination.

. Oil-free compressors are used in case of contact with the product.

. The air used for transporting the caps and maintaining the pressure in the filler bell is always dry and filtered with coalescing (deoiling) and absolute (0.2 μm) filters.

. No chemicals of any kind are stored near the compressors air intakes in order to avoid contamination of the compressed air and consequently of the food products;

. Filtration systems are periodically replaced according to a specific maintenance program.

6) In addition to the rules of good practice that all Galvanina personnel must comply with, maintenance operators must take extreme care when carrying out activities in areas considered to be at high risk of contamination.

b) The use of equipment such as screwdrivers, pliers, etc. in case of contact with parts which are in contact with the food products, must be sanitized.

It is good practice for each bottling line to always have a minimum stock of spare parts, such as mouth seals, deflectors, straws and complete taps, sanitized and stored according to the correct practice.

Any sterilized and sanitized materials must remain wrapped in special plastic bags until they are replaced, and kept in the dedicated cabinets.

Maintenance workers must use maximum hygiene precautions when replacing the faucet by wearing clean new disposable gloves, headgear and clean coat, mask.

The lubricants used during the maintenance phases, which may come into contact with the packaging and / or the food product, must be approved by the Quality Assurance according to the technical and safety data sheets provided by the Maintenance.

Furthermore, the Maintenance must keep the list of lubricants used updated.

Lubricants:

. They are food grade, classified as H1 by the USDA, if there is a risk of accidental contact with the finished product.

. The carbon dioxide used for the production of sparkling mineral water and beverages complies with the technical specifications and current legislation and is of natural origin.

The pallets used inside the plant must comply with the minimum hygiene requirements; wooden pallets are used in the storage warehouse and in the packaging area (where the product is not exposed) while the plastic pallets are used in the syrup room. Upon receipt, they are checked and, if they have the following defects, they are not used in production and are rejected, since they can compromise the quality and safety of the finished products.

Critical Defects:

. Evident pest contamination (rodent or bird droppings).

. Clear contamination from pieces of glass.

. Contamination with live or dead insect populations.

. Pallets treated with chemical products.

. Smell.

Important Defects:

. Broken sleepers.

. Plinths that protrude more than 2 cm from the pallet platform.

. Broken hooves.

. Debris, excessive dust or mold.

. More than two nails protruding 1 cm from the crosspieces, or a nail that protrudes more than 2 cm.

. Any nail that overflows the perimeter of the pallet.

. Splinters that can be easily removed with minimal effort.

. The plastic pallets must be durable and must not splinter; they must not contain foreign bodies and must be easy to clean.

6. 117.80 Processes and controls

a) General

1) At the Galvanina plant there are two production lines, one for Still and Carbonated Mineral Water, the other for Flavored Waters, Sodas and Teas. All the beverages are bottled in glass bottles with aluminium screw caps.

All the sanitation procedures for food and non-food contact surfaces and equipments are described in the **PRO. 7.5.07** "Cleaning and sanitation procedures" (see attached).

2) – 3) The QCM is responsible for the monitoring plan, the supervision of cleaning functions and the purchase of products for the sanitization and cleaning of the systems and equipment of the company. Safety information sheets for these products are kept in the laboratory. Information sheets on their use are displayed in the areas where they are used. Cleaning operations are carried out by operatives of a specialized external company. Sanitization operations are the responsibility of Function Supervisors.

The products, methods, times, frequency and temperatures used in the various operative phases of cleaning and sanitization are chosen by the QCM according to the following criteria:

- ✓ Analysis of risks;
- ✓ Results of analysis checks;
- ✓ Technical knowledge and knowledge of specific hygiene problems of the facility;
- ✓ Information on companies working in the bottling industry;
- ✓ Technical and safety information sheets in which the conditions of use and dosages of the various products used are defined;
- ✓ Indications provided by suppliers of products for cleaning and sanitization.

Cleaning and sanitization are carried out on machines and systems by operatives of a specialized external company and by Function Supervisors, who are responsible for the correct performance and results of cleaning and sanitization activities.

Cleaning of the machines/systems used in the production process has been defined in a series of operative instructions indicating operative methods and the records to be filed:

IST. 7.5.03 "SANITIZATION AND RINSING WITH CIP"

IST. 7.5.01 "CLEANING OF COLLECTION SYSTEMS AND TANKS"

IST. 7.5.28 "SANITIZATION OF SYRUP ROOM"

IST. 7.5.28/A "CLEANING AND SANITIZATION OF SPACES AND EQUIPMENT"

In general, cleaning and sanitization are carried out at the end of the working day. Rinsing operations are normally performed with every product change. If a change is made from a sugar-containing drink to a flavored water during the production day, sanitization operations are carried out.

Internal components of systems that can be dismantled are cleaned with every production change, ensuring that the components are reassembled only after having been sanitized and subsequently rinsed.

Operative methods are defined in **IST. 7.5.28 A** "Cleaning and Sanitization of Spaces and Equipment".

External parts of systems and machines are cleaned by the operatives of a specialized external company, at weekly intervals for the Red Area, and by rotation at least once a week for the Yellow Area.

4) No Allergens are present or introduced in the facility.

5) The Cleaning and Sanitization of the deaeration-saturation and filling plants is planned weekly by the Production Manager based on the productions schedules, and carried out by the operators assigned to the filler.

The effectiveness of the sanitization procedure is monitored by measuring the temperature of the water used and the amount of sanitizer (peracetic acid) present inside the machine during the sanitization (≥100 ppm, ≤200 ppm), using indicator strips (Quantofix Peroxide 100, Peracetic acid 500) at every stage of the sanitization procedure.

The effectiveness of the rinsing procedure is monitored by checking, using indicator strips, the absence (≤1 ppm) of the sanitizer (peracetic acid) in the final rinsing water and inside the machine after the final rinsing. The results are recorded by the operators in the **MOD. 48 CCP2-CCP3**.

If, during the sanitization, the test with the strips does not succeed, the sanitization procedure is repeated until the indicator strip shows the presence of the correct amount of sanitizer, as described in the **TAB. 7.5.06** (see attached). The Quality Control department implements and records the Corrective Action/s by filling the **MOD. 07**, following the **PRO. 8.5.01**.

The Rinsing machine operators check, every 60 minutes, the absence (≤1 ppm), in the water residues inside the bottles, of the sanitizer (peracetic acid), using indicator strips (Quantofix Peroxide 25). The nozzels centering and the water pressure is also checked to ensure that all the bottles are rinsed properly. The results of the checks are recorded in the **MOD. 53.**

The laboratory technicians check daily that the operators perform the preventive control correctly and sign the **MOD. 48 CCP2-CCP3** for approval. The Quality Control department periodically performs a documentary check and signs the **MOD. 48 CCP2-CCP3**, and, eventually, the **MOD. 07**, for approval.

The laboratory technicians take a sample daily, as described in the Control plan **TAB. 7.5.06**, to be tested for the absence of *Escherichia coli* and *Pseudomonas Aeruginosa*. In case of NC, the Food Safety Team is informed and a corrective action procedure is activated, following the **PRO. 8.5.01**.

The accuracy of the test strips is periodically verified by the internal laboratory using samples at known concentration of peracetic acid, following the **IST 8.2.33**.

All the operators and technicians performing the monitoring receive specific training once a year (see the training program and registry attached).

6) The Quality Control department, with the supervision of the PCQI, identifies and marks all the affected product with the **MOD. 08** and implements and records the Corrective Action by filling the **MOD. 07**, following the **PRO. 8.5.01**. The production line stops until the Corrective Action is implemented and approved by the QCM. The **PRO. 8.5.01** defines if and when the product must be rejected, treated or processed.

b) Raw materials and other ingredients

The control and management of the suppliers, regarding the quality of the supplies, is the responsibility of the Quality Assurance department, which provides, as far as it is concerned, for the eventual approval of new materials and new suppliers.

Upon arrival of the goods, the controls required by the Control Plan are carried out, in particular the Warehouse Attendant Employee assigned to discharge or, in the case of raw materials, the QC, checks the integrity of the packaging and their hygienic conditions.

During each delivery, at the end of the vehicle unloading operations, once the required checks have been completed (compliance of the transport document relatively to the order, compliance of the transport document relatively to the goods delivered, visual checks to evaluate the status of the goods), the Warehouse Manager, in cooperation with the Quality Control, collects representative samples of the goods, in order to verify the conformity of what has just been delivered.

The information contained in the declarations of conformity accompanying the shipments must correspond to the purchase specifications.

These documents, after verification, are archived by the Quality Control Manager.

If the material, following the checks carried out, complies with the specifications, the use in production is authorized; if the material is not compliant, it is isolated, pending further decisions.

Particular attention is paid to the control of sensitive raw materials (in contact with the product - bottles and caps).

The plant provides the Purchasing Office with the volumes of raw materials needed to carry out the production activities and the latter formalizes the order to a qualified supplier (based on the list of qualified suppliers updated by Quality Assurance), for that specific material.

In the case of a new supplier proposal or change of specifications with the supplier in progress, the following procedure must be followed:

. acquisition of all technical documentation related to the new material (technical data sheets, declarations of suitability for contact with food, safety data sheets, technical drawings);

. audit to the supplier (in the case of sensitive materials);

. sending a sample for laboratory tests;

. request for supply and sending of samples for industrial testing;

. execution of the industrial test;

. if all the previous phases had a positive result, the supplier and the material are qualified by the Quality Assurance department.

This procedure aims to guarantee the safety and quality of the product, in relation to the specific regulations in force and the good machinability and yield of the new material on our plants.

The arrangement of the pallets placed on the floor must be such as to:

. guarantee the safety of operators during handling, parking and eventual evacuation in the event of an emergency;

. avoid damage to the stored goods;

. allow proper cleaning of all surfaces;

. allow the control of the disinfestation systems;

. allow the correct opening and closing of doors and gates.

Food raw materials, packaging and finished product external warehouse

Inside this warehouse, the materials used on the production lines are stored on pallets, which are placed directly on the floor.

The warehouse operator must pay attention to:

. not place the pallets on uneven, wet or dirty surfaces;

. stow the raw materials in the areas provided for the different product categories and in such a way as to guarantee the management of F.I.F.O. stocks;

Storage compatibility

The materials stored in the raw materials warehouses are neatly arranged and well separated by type.

c) Manufacturing operations

1) Food equipment and utensils and containers are kept in proper condition by proper cleaning and sanitization. If necessary, the equipment is dismantled for thorough cleaning. **IST 7.5.28 A**

Production machines cleaning: they can be divided into ordinary cleaning performed weekly by production personnel and extraordinary cleaning. Ordinary cleaning maintains a good hygienic level in the environment and production facilities, in order to obtain quality products.

The following operations are carried out: cleaning of floors, removal of glass from machines and conveyor belts, cleaning of labeling machines, emptying and washing of washing machine tanks, elimination of waste produced during production, coarse cleaning of machines, cleaning of hoppers and capping machines. With the extraordinary cleaning, parts of systems that are not subject to daily cleaning are cleaned (electrical conduits, conveyor belts, palletizers, motors, etc.). The extraordinary cleaning is carried out following the cleaning programs prepared by Quality Assurance.

The sanitization of the filling machines is carried out using automatic CIP (Cleaning In Place) systems. The fillers are also subject to external sanitization with foaming products applied through special foaming systems.

2) All food manufacturing, processing, packing, and holding are conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, contamination of food, and deterioration of food.

The controls are planned in **TAB. 7.5.06.**

7. 117.93 Warehousing and distribution

The pallets of finished mineral water and non-alcoholic beverages are transported on pallets from the end of the line to the storage warehouse using electric traction transport carts.

The pallets must be stowed homogeneously, distinguished by product code and production batches.

The pallets must be positioned:

. leaving the emergency exits and the doors / gates of access to the room clear;

. leaving the extinguishers installed on walls and pillars accessible;

. in order to allow the cleaning and the control of the disinfestation systems;

. the warehouse must never contain any chemicals of any kind.

Rotation of stored product

The storage of the products is carried out by production lot and by finished product code and the shipment follows the regular rotation of the F.I.F.O. (always the oldest product in stock is shipped).

The trucks in the loading areas during the loading and unloading operations must have the engine off.

The trucks must be suitable for the transport of food products: clean and there must be no products that could cause contamination (detergents, chemicals, etc.), before being loaded they are inspected by Galvanina personnel.

The simultaneous transport of mineral water and foreign substances / products (detergents, chemicals, odorous foods, etc.) is prohibited.

Particular attention must be placed on the presence of refrigerated trucks or, in any case, with insulated cells, whose access to the plant is not a usual occurrence: the absence of odors of any kind and of residues of substances potentially causing contamination must be absolutely verified before the loading operations.

In case of inadequacy or suspicion, the load is blocked and the Quality Control department is informed.

When the trailer leaves the plant, the load must be perfectly covered, so that the bottles are protected from sunlight, dust, rain and anything else that could compromise the quality of the product.

In the case of transport with containers, the "Seven Points" are observed with the relative check list for the acceptance of the containers and all the other customs provisions for the shipment.

Material traceability and traceability of the finished product are of fundamental importance in order to be able to limit potential problems and the recall of the product from the market in the event of non-compliance. It is guaranteed by using the Ad hoc software.

In order to be able to apply the specific operating instructions and procedures, the finished product must always possess a clearly visible printed batch code with indelible technique.

Galvanina products have an hourly lot code indicated on the cap or on the bottle body and a product code placed on the pallet for products destined for abroad.

The identification of the lot and of the Best Before date is reported on each individual bottle following what is defined by current legislation.

The durability period (Best Before) depends on the type of product.

8. 117.110 Defect action levels

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

On the production lines, an electronic inspection machine checks the presence of the cap and the water level inside the bottles, if a non-compliance is found, the bottle is discarded automatically.

The aluminium caps are periodically checked for non-compliances on their structure by the laboratory technicians, following the **MOD. 157** and the **TAB. 7.5.06** (see attached).

The glass bottles are periodically checked for non-compliances on their structure by the laboratory technicians, following the **MOD. 158** and the **TAB. 7.5.06** (see attached).

The operators check, at the beginning of each production and every 30 minutes, the level of carbonation, expressed in g/L of CO_2 dissolved in the water, following the **IST. 8.2.10** and recording the results in the **MOD. 54 A** (see attached).

The operators periodically check the correct functioning of the labeling machine and fill the **MOD. 52** (see attached).

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	La Galvanina S.p.A.	Site Code	9439107
Site name	La Galvanina S.p.A.		
Scope of audit	Exploitation and bottling of mineral water in glass. Production of soft drinks and flavoured water in glass bottles.		
Exclusions from scope	Trade goods		
Justification for exclusion	Traded goods on producer's brand, company brand and private label are fully outsourced products realized by other legal entities.		
Audit Finish Date	2019-03-20		
Re-audit due date	2020-03-16		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Head Office	Yes

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2018-03-13		
Certificate issue date	2019-05-03	Certificate expiry date	2020-04-27		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	3

3.Company Details

Address	Via della Torretta, 2 47923 - RIMINI (RIMINI)		
Country	ITALY	Site Tel. Number	+39 0541 751315
Commercial representative Name	Manuela Pazzaglia	Email	manuela.pazzaglia@galvanina.com
Technical representative Name	Matteo Spinozzi	Email	matteo.spinozzi@galvanina.com

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3

Shift Pattern	2 time 06.00-14.00/14.00-22.00
Subcontracted processes	No
Other certificates held	IFS, ISO 14001, ISO 18001, Organic, NOP, Kosher.
Regions exported to	Europe North America Oceania Asia Other Choose a region
Company registration number	304/2007
Major changes since last BRC audit	Elimination of line VAP.

Company Description

The company is composed of 2 sites both IFS certified, located in Val di Meti and (the present site) in Rimini.
The covered site area of the company is 7.800 square meters.
Sanitary authorization: n° 304/2007.
FDA number: 10567555272
The production process consists of pipelines and storage tanks of mineral water, depalletizer for empty bottle visual control before entering the washing equipment for glass bottles, washing, sanitizing and rinse of bottles, filler, capper, control for caps presence, labeller, printing the lot number and expiry date, wrapping or cardboard packer and palletizing. For the preparation of soft drinks dissolvers are used to warm for the ingredients, mixing, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers.
2 production lines and 30 full-time employees working on 2 shifts work. 3 HACCP Plans
Dispatch turnover between national / exported products within Europe / exported products extra Europe is USA/CAN 85%, Europe 5%, ITA 10%; percentage (turnover) for retail branded products about 85%.
Other schemes for the Company are IFS, UNI 10854, ISO 9001:08, ISO 14001:2004, OHSAS 18000:2007, ISO 50001:2011, Organic, Kosher and AEO_F.

4.Company Profile

The name and contact data of the contact people are Matteo Spinozzi, matteo.spinozzi@galvanina.com and Matteo Matassoni, matteo.matassoni@galvanina.com Tel. 0541751315 Fax 0541-752510. IFS combination Audit. BRC Logo correctly used

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC, please contact tellus@brcglobalstandards.com

5.Product Characteristics

Product categories	12 - Beverages Category Category Category				
Finished product safety rationale	Low PH (<3,3), presence of CO2 and pasteurization at >90°C and >150UP				
High care	No	High risk	No	Ambient high care	No
Justification for area	Enclosed Area or low risk area: stable product. Microbiological low risk area due to ambient stable product (e.g. PH, pasteurization).				
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen				
Product claims made e.g. IP, organic	Organic, Kosher, sugar free, ISO 14001, OHSAS 18001, ISO 5001				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Organic Lemonade 355 ml in glass private label Jas, Chinotto 1L in glass private label Natura S; Sparkling water 1L for A.				

6.Audit Duration Details

On-site duration	16 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	extra time 0,5 MD added for the IFS 'combined' audit		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-03-18	10-00	19-00
2	2019-03-19	08-30	19-30
3	2019-03-20	08-30	13-30

	Auditor (s) number	Name	Role
Auditor Number	176125	Bianca Francia	Lead Auditor
Second Auditor Number	N/A		Auditor

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Patrizia Mini– Board Vice President	X	X	X	X
Matteo Spinozzi - QA Manager	X	X	X	X
Achille Marino– Plant Director	X		X	X
Matteo Matassoni - QC Manager	X	X	X	X
Mauro Bacchini – Prod. Manager		X	X	
Pasquina Arlotti - werehouse		X	X	
Fiorenzo Guidi -R&D		X	X	
Frisoni - operator		X	X	
Pasaresi - operator		X	X	
Di Noto- Operarator		X	X	

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided**	**Date reviewed**	**Reviewed by**
1	4.6.1	A little part of the line 2 was not completely covered before empty bottles inspector	A new stainless steel cover has been installed before the empty bottles inspector	We did not consider the absence of cover to be a risk in this step. During the annual Flow Chart revision more attention must be paid to production line	A new stainless steel cover has been installed before the empty bottles inspector. (See pictures of the before and after the installation of the cover)	2019-04-01	Bianca Francia
2	5.4.3	The traceability documents of lemon Juice of A. supplier doesn't specify the provenience (SICILY) anyway the technical specification report 100% Sicily provenience	A traceability test has been commissioned to A. supplier to verify the provenience (SICILY) of the lemon Juice. An accompanying documentation on the provenience (SICILY) of the Sicilian lemon Juice has been requested to the supplier	The BRC guidelines were not correctly interpreted. A meeting has been arranged together with the R&D manager to better understand BRC Standard requirement. Additional specific training was provided to the quality control employees to ensure that the accompanying documents of the lemon juice from A. supplier specify the	A traceability test documentation received by A. supplier to verify the provenience (SICILY) of the lemon Juice. (See documentation provided). A new personnel training on correct check of the accompanying documents has been carried out.	2019-04-01	Bianca Francia

				provenience (SICILY).	(See MOD. 35 attached)		
3	5.4.4	In the past 6 months, the traceability test was not performed for Products with 100% Sicilian Juice.	A new traceability test and mass balance were performed for Products with 100% Sicilian Juice	The BRC guidelines were not correctly interpreted. A meeting has been arranged together with the R&D manager to better understand BRC Standard requirement	Internal traceability test and mass balance for Products with 100% Sicilian Juice. (See documentation provided)	2019-04-01	Bianca Francia

Comments on non-conformities

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Company policy of 2018-03 re-approved during last management review of 2019-03-07 followed by monthly meetings done usually in the mid of the month, last done on 2019-03-07 with objective target analysis and trend against target done each month together with relevant KPIs (score card) next is planned for the end of March 2019.

There is an integrated Company policy: Quality, environment and food safety dated 01.2019 which is signed by the Company President Mr Mini is displayed both at the site entrance and other points of the factory, furthermore presented at all levels during training. Refer to 231 model.
PRO DIR 01 "Responsabilità della direzione" issue 6 dated 03/2018. Management review last dated 07.03.2019. Clear targets are set on document enclosed to management review: increase in sales and clients; decrease of complaints.
Quality, legality and food safety parameters are monthly monitored by top management consulting updated results supplied by QA Department and HACCP team. Monitoring shows levels on targets. HACCP plan review base on analysis record- supplier change- R&D activity- processing changes - external alert and new law- recall/withdrawal, sanitization and pest procedures efficiency, with discussion and evaluation outputs as management decisions.
KPI revenue +11%, Number piece/h, NC on food safety <1.
Meeting programme is in place and properly communicated.
Seen all monthly records of 2019, e.g. that of 07.03.2019 and 14.02.2019.
The objectives are analysed at least quarterly
The company's senior management thanks to Food Companies Association is kept informed of scientific and technical developments, industry codes of practice and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.

Confirm the structure of the monthly communication/meeting programme.
Employees are aware of the need to report any evidence of unsafe or out-of-specification product or raw materials, to a designated manager to enable the resolution. Questionnaire have been submitted to all personnel in order to verified food safety culture with good results.
The site provides and ensures confidential reporting systems by confidential segnalations.

The company use BRC logo on web site and be to be communication in conforming metter.

Since previous audit there were 3 customers second party audits (Conad, Eurospin, Lidl), Halal, Kosher, Organic audits, all with site re-approval as well as one IFS integrity audit, last one without any kind of non-conformity (positive result).
Previous 4 minors audit NCs closed by CAs implemented without further recurrence.

1.2 Organisational structure, responsibilities and management authority

Overview of Management Structure verified. Monitoring shows levels on targets. KPI are related to HACCP plan review base on analysis record- supplier change- R&D activity- processing changes- external alert and new law- recall/withdrawal, sanitization and pest procedures efficiency, with discussion and evaluation outputs as management decisions. Es. Kpi ppm of complaint, analysis results, NC ecc..
Operators are sensitized and aware of their own skills and responsibilities, all staff have access to relevant procedures.
TAB 5.5.01 "Organigramma nominativo" dated 06.03.2019. Job description in place for all managers and supervisors and responsibilities, substitutes in a dedicated attachment with all signs including substitutes. Job descriptions were in place. Duties are defined in job descriptions.

2 The Food Safety Plan – HACCP

HACCP Study and Manual PR 7.5.03 "Sistema di autocontrollo aziendale" last updates (now version 16) 09.01.2019.
The program prerequisites discussed in the Manual and HACCP procedures.

Prerequisite programs defined and adequately demonstrate that basic conditions are being provided for the safe production of food.
Hazard Analysis verified.
Literature data, legislation and customer requirements have been referred to.
Guidelines and codes of practice of reference.
HACCP Team led by Matteo Spinozzi who is trained in and experienced with HACCP, member of team .
The multi-disciplinary team comprises members from the following departments: Direction, Production, Maintenance.
Competencies documented.

A full description of process and products are developed and documented in the HACCP Manual, which includes all relevant information on food safety. The inquiry involves mainly the hygienically and sanitary risks.
Verified the description of products: Water, flavoured drinks and soft drink.
Intended use specified: for al consumers.

Flowcharts are present to different types of products. The flow diagram of the various types of products are reviewed once a year during the Management Review.
Seen flow diagram verified on:

- 15.01.19 for water VAP,
- 22.01.2019 for soft drinks VAP
- 12.11.2018 for flavoured water VAP.

Process steps: extrusion, pasteurization, sugaring, cooling, filtration, bottling and packaging.

All the potential hazards are identified and recorded, the scope of the HACCP plan has been confirmed MHACCP.
Each identified hazard was reviewed and given a risk rating to define the severity and likeliness of hazard occurring. Suitable controls for each hazard were documented, in many cases these formed part of the prerequisite programs.
Significant hazards have been identified as physical, chemical and microbiological.
The team have used a 4 step decision tree.
Last hazard analysis dated 22.11.2018.

HACCP plan with clear reference to EU Reg. and IFS/BRC standards, is generally developed and comprehensive with Codex principles applied in sequenced chapters.
Critical limits had been agreed and signed off by team.
CCPs identified are as follow with relative critical limits:
CCP1 – During bottling, physical risk of foreign bodies contamination on empty glass bottles. CA: electronic inspector with cameras. Critical limits: inspector ≥ 2 mm;
CCP2 – During bottling in glass, chemical hazard as residues of sanitizer or concentration of sanitizer for cleaning process of degasser and saturator equipment. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water;
CCP3 – During bottling at the filling machine, chemical hazard as residues of sanitizer or concentration of rinsing for bottles and rinser equipment cleaning process. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water;
CCP4 – Only for soft drinks During pasteurization of syrup, microbiological risk. CA: Pasteurization temperature. Critical limits: ≥90°C (98 for tea) with 45 seconds of stop;
CCP5 – During rinsing of bottles, chemical risk of sainting presence. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water;
CCP6 – Only for soft drinks During pasteurization of finished product, microbiological hazards for soft drinks, controlled by pasteurization's in tunnel of filled bottles. CA: Pasteurization temperature. Critical limits: 350 PU, min 150 PU, max 900 PU.
Additional foreign body controls with filters on fruit juice, 3 steps at 400/250/50 mm, cleaning and maintenance programs are carried out and monitored as CP
The critical limits for CCPs are clearly defined as above mentioned.
Monitoring procedure defined as follows:

CCP1: Electronic inspector with cameras monitored at start of the line and every hour and at bottles size changing by production staff. Corrective action: if there is a NC parameter the line stops and calibration is repeated until the test is conforming, recorded on MOD 54CCP1_L2;
CCP2: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3;
CCP3: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3;
CCP4: monitored by production staff with data logger for each lot, corrective action block of finished products and evaluation by Quality, organoleptic evaluation carried out, recorded on PC;
CCP5: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3;
CCP6: monitored by production staff with data logger for each lot, corrective action block of finished products and evaluation by Quality, organoleptic evaluation carried out, recorded on PC.

All records are signed by responsible for the monitoring and verified by an authorized person.
Records of monitoring were available and properly managed. Seen ex. Production schedule with record of electronic device dated 14.03.2018. Seen peroxide test in production schedule for CCP2/3/4 MOD 48, seen data logger records for CCP 4/6 dated 13-14.03.2018.
The method of monitoring and corrective actions to be taken in case of deviation. HACCP verification during management review.

Every CP and relative critical limits were validated on 20.01.2016 CCP1 inspector, CIP validation (concentration and analysis) CCP 2,3 line 1 dated 18.09.2016, CCP5 dated 20.04.2017; CCP 6 pasteurization tunnel by SICCA done in date 10.12.2012. CCP4 flash pasteurization done in date 07.01.2014 by internal personnel by check and analysis on yeast and mould, lactic and CBT (72h at 30C).
Validation method of CCPs: Critical limits had been agreed and signed off by team.
All CCPs are validated taking into account legislation, validation studies, industry best practice and commissioning studies.
The company's HACCP plan is based on following updated and comprehensive information
-scientific literature and known hazards associated with drinks and water production
-complaints and customer requirements
-food-safety European legislation
-codes of practice of packing process (Manual of good practices). Manual of good practices on the transport)
The critical limits were validated with bibliographic study, for temperature and litmus paper control (Control Point) was dated December 2017.

Procedures of verification are established to confirm that the HACCP plan, including CCPs are effective.
HACCP plan is reviewed every year during Management Review and/or in case of a production change in ingredients or technology.
Last HACCP review dated 11.12.2018.

3. Food safety and quality management system

3.1 Food safety and quality manual

Quality Manual EM 0 of 03.03.2018 and relative documentation (operative instructions present and some procedures for the management of specific activities) are available on IT company system and by means of controlled paper copies signed for receipt.
Documents are clearly legible in sufficient detail and in appropriate languages (Italian).

3.2 Document Control

Verified the procedures for the Documentation and Registrations Management: PRO Doc 01 issue 7.
The System was working effectively.

3.3 Record completion and maintenance

Verified the procedures for the Documentation and Registrations Management: PRO DIR 01 “Gestione documentazione sistema integrato aziendale” issue 7.

The System was working effectively.

Collection, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality are properly managed.

Records retained for a time consistent with the shelf life of products as indicated on technical sheets:

Shelf life Still Mineral Water in glass and PET is 24 months, Sparkling Mineral Water in glass and PET is 12 months and 15 months for Italian Market, Flavoured Water and Soft drinks have a shelf life from 9 to 12 months.

Records retained for a time consistent with the shelf life of products as indicated on technical sheets (from 6 to 60 months’ months), record keeping 4 years.

Electronic records are automatically backed up every month to an external server to prevent loss

3.4 Internal audits

There is a program of internal audits of the quality systems carried out by the QA Team on refer procedure QMS Manual. Procedures and Audit plan defined in order to guarantee that audits are conducted on those systems and procedures which cover the requirements of the Global Standard for Food Safety.
More auditors are in place to assure independence. Auditors are trained and has Food and Agronomy Degree. Internal audit programme is audited by external consultant.
Dedicated report on purpose. BRC/IFS based check-list.
Internal audits carried out for activities identified as critical to food safety and to product specifications such as sanification and magnets; seen last one dated 31.01.19 and general audit dated 04.03.2019 performed by Rita Barbiei qualified external auditor.

Internal audits scheduled as ongoing and throughout the year activity with more than 4 audits per year not performed. Internal audit scope and frequency according to areas: warehouses/production/mixing areas/other facilities - monthly, internal laboratory and maintenance department-quarterly.

The scope of the internal audit program include the: HACCP or food safety plan, including the activities to implement it (e.g. supplier approval, corrective actions and verification); prerequisite program (e.g. hygiene, pest control); food defence and food fraud prevention plans; procedures implemented to achieve the Standard. Each internal audit within the program have a defined scope and consider a specific activity or section of the HACCP.

Corrective actions are in place in case of non-conformity.
Audit performed by use of check-list dedicated for each audited production area and related GMPs and other procedures implementation level. CAs to be implemented are followed including defined closure target time.

Audit on GMP performed weekly in production area seen record of last dated 15.03.2019 in red are (bottling) and in date 16.03.2019 in staff facility no NC raised.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The site have define a Procedure for PRO 14 Vulnerability and authenticity of products issue 90 dated 01.02.2019.

Diveded raw materials in different class: sugher semolina and liquid sugar, juice (red orange, lemon and grapefruit), other juice, flavours, sweetners, gas. Considered intrinsic factor, availability of test, consider risk to be mitigated risk over 50. Resultest over 50 point Juice of red orange, lemon and grapefruits.

A procedure PRO 7.4.00 “Approvvigionamento” issue 9 dated 25.01.2016 in place dealing with management of suppliers of raw materials, packaging and services and the procedure PRO 7.4.01 “Valutazione, qualificazione e monitoraggio fornitori” issue 9 dated 25.01.2016 relating to evaluation, qualification and monitoring of raw material, packaging and services suppliers.

A Qualified Suppliers List (TAB 7.4.00 “Elenco fornitori qualificati”) updated 2019 based on risk analysis and a qualified raw materials suppliers list (TAB 7.4.00A “Elenco fornitori qualificati materie prime alimentari”) is available updated 12.03.2019.

All suppliers of products and services have to be approved by the Technical Department and entered onto the authorized supplier list before they can be used.

Risk assessment is based on hygiene risk (definite on HACCP plan) and quality impact to the product with suppliers / raw materials: allergen contamination, foreign-bodies risk, micro/chemical contamination, substitution or fraud are taken into account in supplier’s risk assessment. No High risk raw material defined, anyway all raw materials supplier are GFSI certified es. G.

All supplier of pack and raw materials are GFSI certified.

No agents nor brokers are used.

Supplier classified low risk via certification or audits: Seen audit carried out on October 2016 to bottles supplier and certificates dated 2017 for bottles and caps. No high risk suppliers, anyway all raw material supplier are certified GFSI.

Supplier of flavour G., D., A. Orange Agrumaria C. certified BRC 8060459, Wild BRC/IFS certified. Interchim Naringina (Natural aroma for grapefruit). Certified FSCC 22000 FS22-2012/007 exp. Date 06.10.2019.

Pack Resilux certified BRC., closure G. certified FSSC 22 pack. CO2 (technical specification 31.08.2017 natural geothermic extraction, purity 99%). Sugar Global organic BRC site code 1265032

Raw material assessments at intake and sieve analysis form part of the ongoing review of supplier performance.

Raw material assessments at analysis form part of the ongoing review of supplier performance. In case of Out of Specification results of suppliers’ products, batch is rejected and analysis is carried out.ll have an up-to-date list or database of approved suppliers on excel format updated 07.03.3019. The list or relevant components of the database are readily available to the relevant staff (e.g. at goods receipt CQ , procurement, ESQM).

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw materials are assessed on receipt and NCs are fundamental criteria for monitoring and approval of suppliers.
Seen records in transport documents regarding to order conformity, absence of contamination, quality, integrity, expiry date, analysis, according to internal procedure
In incoming on juice Mod 36C control of temperature for frozen juice, check correspondence with ddt (batch and exp. date) and present of analysis.

Seen incoming check of Lemon Juice 32Brix, sugar incoming check

Internal lab performed analysis

Seen analysis of supplier es. Lemon Juice Agrumaria CoA 25/07/2018.

3.5.3 Management of suppliers of services

Service suppliers are managed through audit (seen last one dated November 2018 for pest control supplier) and questionnaire.
List of supplier of services: cleaning, pest control (Rentokil), lab analysis (Eurofins, Biomieux) and transport (MSC, YAN).
Contracts are available and yearly renewed.
Complaints and issues monitored and used for a score card.
Questionnaires are updated every three years, seen last compiled questionnaires sent by suppliers on 2018 (seen questionnaire of pest control and lab analysis suppliers).

3.5.4 Management of Out sourced processing

NA

3.6 Specifications

The various kinds of specifications were verified for availability (dedicated files managed according to the rules defined in the Quality Manual). Specifications resulted being updated and available to interested staff. Specifications kept in SW system.
The following specification were verified on site:
- Raw materials “Aroma Naturale Giotti” dated 2015-04-08; citric acid dated 2015-03-18 and CO2 dated 13.02.2015.
- CO2 Rivoira 99% 17.01.2017 E290. Natural extraction 13.02.2015.
- Packaging closure26.02.16.
- citric acids E330 dated 03.06.2018 supplier Faravelli spa
- Ascorbic acid G. dated 15.09.2016
- Cane sugar 12.04.2018
- Lemon brix 32 aseptic updated 22.02.2017 Italian
- blood orange concentrate Agrumaria 50 brix (-18C) 22.02.2017 not specified the provenience but available Supplier declaration dated 19.03.2019 on Sicilian provenience.
- lemon aroma dated 15.09.16, Chinotto infuse natural 01.2018 supplier Caffo.

During document review and traceability exercise the following specifications were verified:
- La Galvanina Sparkling water dated 2016.
- Pueraqua 09.11.2017 (sparkling water for Aldi USA)
- Soda lemon 30.10.17 cod 058203 570 ml wf.
- Blood orange K 750 ml cod 046450 updated 18.01.2018 and receipt 19.05.2016
- Lemonsoda BACI & B cod 072002 18.04.2018
- Chinotto Ecor cod 09605 dated 20.07.2017

These are reviewed minimum every three years or in the event of any change.
Rules are defined for the communication from supplier in the event of change/updating of characteristic.

3.7 Corrective and preventive actions

There is a documented procedure for handling non-conformances identified within the scope of this Standard: PRO 8.5.01 “NC/AC/AP” issue 5 dated 02/10/2009.
Seen appropriate examples of CA management recorded on dedicated data base.
All CA/PA sheets contain suitable root cause analysis and verification on effectiveness.

Properly documented on company network dedicated Form. Action taken within short time. QAM in charge and signs the closure of corrective action implemented. CAs properly implemented with identification of the cause and relative corrective action, positive trend observed. QAM is in charge for CA implementation. Regularly done as described in the procedure.
1 CAs in 2018. Seen CAR dated 27.02.2019 for mistake in cleaning. Done training to operator.

3.8 Control of non-conforming product

NC managed by software and pc: procedure PRO 8.5.01 “NC/AC/AP” issue 5 dated 02/10/2009

Clear process well understood by staff interviewed during the audit according to procedure described.

No major trends considering the very large number of produced goods. In general NC are detected directly during process controls and consequently managed real time. The number of NC is part of KPI/objectives. Seen appropriate management of NC product during the audit.

In case of NC product, the product is subject to physical separation and quarantine stock. Quality Control (after lab analysis check) has authority for releasing product.

Records of NCs are maintained and properly kept.

In 2018: 5 NCs were raised.

Seen NC dated 27.02.2019 for taste non-conforming. Root cause non-conforming cleaning and rising of machine and taste by operators at production start up. CA training to operators done 27.02.2019.

Seen NC dated 09.03.2019 for container of raw material grapefruit juice damaged.

3.9 Traceability

Traceability Systems is defined in the dedicated procedure available and implemented for raw materials, finished products and packaging materials: PRO 7.5.06 “Procedura rintracciabilità” issue 9 dated 09.2013. Verified the IST 7.5.07 VDM “Predisposizione lotto di produzione” for lots control properly registered on production sheets. The responsibilities were determined.
Traceability system operates through IT system enables trace of incoming, other production phase and ingredients and packaging from supplier through processes, to packing and despatch are traced by paper records.
In case of rework materials traceability is maintained and test carried out.
Upstream traceability tested regularly done, mass balance product to customer.
Traceability test carried out every year to cover both directions (from raw materials to finished product and vice versa).

A traceability test was conducted by the Company form raw materials Flavour Biscuit
L0005085593 arrived in date 29.10.2018. Since final products LTB023A1900L1 production date 01.23.2019 exp. date bb 23.01.2020 .
A traceability test was conducted by the Company from final products Pink Grapefruit organic wolwfood mkt 750ml L TB036 A1900L1 produced 27084 bt, sold 96 and in storage26988 in storage. verified traceability of pack materials, black caroots juice, pink grapefruir, flovour, sugar and citric acids. sine prodcution records dated 05.02.2019. Seen data logger for pastourization 70C, absence of glass brekeage. Seen raw materials analysis e.g. organic cane sugar 05.09.2018, analysi Co2 Rivoira 17.01.2019 and oprganic black carrots 14.06.2018.

None suppliers approved by questionnaire.

A traceability test conducted by the auditor in the day of the audit was conducted on the product Soft dringk SODA Blood orange L 0,750. Privet label Sprout.
Production date 22.01.2019, batch TB 022a1900L1, expiring on 22.01.2021. The auditor independently chooses the sample for the test from sample area. Mass balance verified with quantity produced and sold (9024 bottles). time: 20 minutes.
Seen production records of Juice mixing with batch L 32030 for blood orange Juice, sugar, flavour record on Mod 456 V dated 22.01.2019. Filter check 50 micron.
CCP 1 sanification of Line
CCP 2 tank 5 sanification in date 21.02.2019 and rising check ph .
CCP 5 rising machine sanifcation check. Nessuna rottura vetro.

CCP6 pasteurization record 92C signed by responsible
Seen Analysis mb and chemicals 22.01.2019, Co2 5.8, PH 2.7, yeast, mould & lactic, stabity test 30C per 7 days.
Seen Specification of raw materials and receipt.

A traceability test conducted by the auditor in the day of the audit
was conducted on the product 6X1000 ML GALVANINA US O. BLOOD ORANGE 16% CODE 075931. Production date 25/01/2019, batch
19.JA.25, expiring on APR.25.20. The auditor independently
choose the sample for the test from warehouse. Beverage preparation dated 23-24/01/2019 cod 075931, analysis dated 25.01.2019. Recieot 16% juice 075931 dated 13.09.2017. Absence of brekeage during bottling. Co2 analysis dated 05.12.2018. Mass balance
verified with quantity produced and sold. time: 2h.

3.10 Complaint-handling

The procedure for the management of the complaint handling was defined. The responsibility was determined: 8.5.01 “NC/AC/AP” issue 5 on 2/10/09.

Positive trend over last years. System in course of update for better information including final consumers. QAM is in charge. Customer complaint analysis data included as input during management review. Complaints is a target of KPI system.

Complaints logged by customer services department are handed to technical department for investigation. The Customer Complaints Investigation report form included consideration of root cause.

Complaints data was summarised and reported weekly. Complaints per million units (CPMU) was monitored continuously and reviewed at management review meetings.

In 2018, 4 complaints raised from retailers 1 for closure, 1 for label and 2 for gas. No complaints from consumers nor authorities; no complaints related to foreign material found in finished products.

3.11 Management of incidents, product withdrawal and product recall

Procedure defines the key personnel who manage the incident management team: PRO 9.00 VDM “Gestione sicurezza aziendale ed emergenza” issue 3 del 14/5/12.
The responsibilities were determined.
The company has documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality.
The procedure indicate, to call the certification body in 3 working days in case of real recall.
Crisis team defined including QAM and Company vice president.

The process was tested on 11.03.2019 on Arancia Bionda 1L L 327/18 with client Ecor Natura Si. Mock cause: physical foreign body. Seen mail to client and mass balance. Seen raw material provenance and batch Seen traceability of batch, recall mail and crisis team summoned. Time: 2h.

No recalls nor withdrawals in the last year

4. Site standards

4.1 External standards

The building was on good condition.
In good repair and well maintained with investments regularly planned. Located in a large, light industrial estate with green fields around the plant. No local activities that would risk product contamination.
Adequate maintenance of the site and in relation to pests.

4.2 Site security and food defence

Procedure is in place defined on refer risk assessment: PRO 11.00 "Procedura Food Defence", issue 1 dated 08/01/14.
Team food defence team leader Matteo Spinozzi.
Last security risk assessment dated 31.01.2019.
Last alert test performed 14.03.2019.
Sanitary authorization: 304/2007.
FDA number 10567555272.
Staff have been trained in site security procedures and food defence during annual training. Last training on food defence was carried out on 15.03.2019.
Enclosed site with 24 hour security, by external evaluated supplier Vigilance service in continuous. A visitor was registered systematically.
Controlled access for all external people by approval only. Plant area is surrounded by fence and gate.
Documented Food Defence on procedure. The procedure to maintain the site security defined.

Where raw materials or products are identified as being at particular risk, the threat assessment plan are include controls to mitigate these risks. Seen supplier evaluation. Mitigation plan present for Orange and lemon juice by analytical determination planned.

Areas where a significant risk is identified are defined, monitored and controlled by alarm system and video surveiance. These shall include external storage and intake points for products and raw materials (including packaging).

Staff and visitors have access to the site by registration to ensure that unauthorised access is not permitted.

4.3 Layout, product flow and segregation

Site map in place which meets the requirement and define access points, personnel, waste, location of staff facilities and smoking areas.
Area present on site:
- Production area
- Warehouse

The layout of the plant is adequate and functional, updated map of the plant in HACCP Manual.
The local production and warehouse are adequately separated in order to minimize the risk of contamination. It was not detected any environmental risk. Storage areas are in line with the requirements of the standard.
The areas are all defined as low risk. The HACCP manual defines all areas at low risk because it is stable products.
No High risk/care area on site.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The factory is suitable for the intended purpose.
The walls are designed, constructed, finished and maintained to prevent the accumulation of dirt and to minimise condensation and mould growth. The cleaning operation is facilitated.
The floors are adequate and maintained in good repair.
Drainage doesn't pose risks for product contamination and not compromise product safety.
Ceiling are proper managed and suspended tools and pipelines are under control.
Windows have mosquito nets that prevent the ingress of pests properly maintained.
External doors to raw material handling, processing, packing and storage areas are closed to prevent pest ingress.
The lighting ensure a safe environment to carry out processes, inspection and cleaning operation: seen protection on light to avoid possible glass contamination.

Ventilation is conforming and maintenance of filters of conditioned air used is documented.

4.5 Utilities – water, ice, air and other gases

Procedure for water management in HACCP manual.
Potable water in use available from spring source.
A schematic plan of water is available dated 2016.
Relevant records are maintained. Pluming system map detailing all sampling points was available.
Water is tested every year for microbiological (including TMC, E.Coli, Coliforms and Enterococcus) and chemical (including heavy metals) parameters with reference to Circolare 17 dated 1991, DM 10.02.2015 and DL 08.10.2011.
Internally weekly check done by internal lab seen record of November 2018 and march 2019.
Analysis are carried out by internal and external accredited (micro and chemical) lab Università di Camerino and Neotron (Accredia 0026). Seen analysis of Università di Camerino dated 13.04.2018 sorgente Galvanina.
Microbiological test of spring water done every 3 months last Lab CSA Accredia 0181 dated 20.12.2018 with Speudomonas aeruginosa 0.No use of non- potable nor recycled water.

STEAM is not into contact with food.

4.6 Equipment

The plants used in production are fit for purpose and well washed. SS used.

Main equipment was well maintained under routine maintenance systems.

Equipment contact surfaces all SS 316 but predate certification. Engineers aware of the requirement.

The production process provides 2 bottling lines, one for GLASS, equipment consist of pipelines and storage tanks of mineral water, discharge glass bottles, washing machine for VAR and rinser for VAP, filler, capper, inspector for caps presence, labeller, printing the lot number and expiry date, wrapping and palletizing. For the preparation of soft drinks dissolvers are used to warm for the ingredients, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers. Tunnel pasteurization for bottles for soft drinks.

Minor car 1of 3.

4.7 Maintenance

PRO 6.3.01 “Manutenzione apparecchiature ed impianti” issue 8 dated 15/05/2012 .
4 maintenance workers who operates computerised maintenance plan and procedure, with workshop area which is maintained in good hygienic condition.
Refrigeration equipment subcontracted to specialists on case of breakdowns equipment.
The maintenance and cleaning operations activity was processed to ensure the safety of products.
The materials used for equipment and plant maintenance were conforming to use.
The good conditions are guaranteed during the maintenance programmed.
The Contractors involved in maintenance activity was monitored by the Responsible of the maintenance process.
The maintenance programs were verified.
Maintenance team regularly trained for proper GMPs and GHPs respect during maintenance activity. Operative instructions on purpose.
No major breakdowns during last 12 months.
Documented hygiene inspection on start-up completed by production supervisors. Seen records of control performed on production record dated 18.03.2019.
Food grade lubricants are used: No allergens in food lubricants. Food Grade Oil Food Spray NSF-H1.
Engineering workshops are kept clean and tidy and controls are in place to prevent transfer of engineering debris to production or storage areas.
Last maintenance records seen dated 28.12.2018: on GLASS filling machine.

4.8 Staff facilities

Single large changing facility within main building maintained in clean condition by dedicated cleaning staff.
Facilities for hand washing is sufficient
The canteen facilities were not present.
The staff facilities are adequate. The cabinets are sufficient to receive the personal effects of the operators and are equipped with double compartment to separate work clothes from street clothes.
Washing hands before entering the production departments.
The number of sinks is adequate and the toilets are adequately separated from production areas. There is a refreshment room for short snacks through vending machine. Placards posted on proper hygiene.
The HACCP Manual describes the Rules of Conduct staff.
Toilets are adequately segregated and do not open directly into production, packing and storage areas. Toilets are provided with conforming hand washing.
Smoking is not permitted inside the plant. Dedicate areas for smoking was identified on external perimeter of building.
No high care/risk facilities.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Chemical and physical product contamination control is described on HACCP plan and it is properly managed.
The storage, handling and use of chemical products is well managed to prevent chemical contamination.
Chemical products are clearly identified and correctly segregated and locked.
Seen Material Safety Data Sheet of the sanitizing products and the Technical Specifications.
All chemical containers labelled and stored in a segregated and closed metallic locker managed by authorized staff only.
Chemical products used for cleaning are present. Only food grade chemical used in production areas.
Material Safety Data Sheets are available.
Cleaning chemicals stored in a locked room, restricted access on external storage area.
Chemicals were well controlled within the factory as all containers labelled and dispensed via dosers. Cleaning chemicals stored in a locked room, restricted access.
A list of approved chemicals used at the facility was maintained for maintenance and
cleaning chemicals. General Chemical awareness training was given to personnel at induction. Food grade lubricants policy in place.
Cleaning chemicals were supplied against specifications. Food suitability was documented for chemicals used on site.
Cleaners were formally trained in-house and in chemical handling by chemical supplier where required. Es. Peracetic acid and soda. Divosan and Divoflow.

4.9.2 Metal control

Snap-off blades are used only in packaging area. The knives management is verified every day with the pre-operative control before the beginning of production day.

Documented knife policy. The knife is used on packaging area; the monitoring was documented on start up control.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The procedure of breaking glass on production area in glass was documented on HACCP Plan. In case of a glass breakage an “incident report” is opened and investigated following the operative instruction.
Daily start up control and monthly glass and hard plastic audits.
A list items detailing location, number, type and condition of glass is in place; recorded checks of condition of items and details on cleaning or replacing items to minimise potential for product contamination are in place.
During the audit, auditor has checked randomly windows and glasses present in the glass list.
Seen glass of windows during audit: all conforming.
Glass and similar material are listed on the Glass Register.(check list Mod. 185 VDM “Checklist vetri e plastiche dure” issue 2 seen dated 07.01.2019). Glass and hard clear register was risk assessed and items audited daily, and weekly according to risk, seen record dated 18.03.2019. No glass incidents to date. Staff well trained in process and mock incident has taken place for training.

4.9.4 Products packed into glass or other brittle containers

The procedures (PRO 7.5.00 "Gestione bottiglie vuote" issue 1 ; IST 7.5.29 issue 9 updated 11.01.2016 Gestione scoppio bottiglie) for handling glass, brittle or hard plastic, ceramic or other materials includes the requirement to inspect with a weekly frequency. Verified in production records check.
Bottles are cleaned using rinser before filling, mineral water and Peracetic acid are used for controlling foreign objects in empty bottles. A procedure is in place for filling phase checks: MOD 54 VDM-V "Controlli riempimento" issue 5.
The storage of the glass containers is segregated from the storage of raw materials, product and other packaging.
Even if no breakages occur, records are properly maintained, record are reviewed every year during management review to identified the trends.
The procedure of breaking glass on production area in glass was documented on HACCP Plan. In case of a glass breakage an "incident report" is opened and investigated following the operative instruction.
In more details, when a breakage occurs, the following action are taken: removal and disposal of at-risk products near the breakage; immediate and effective cleaning of the line; documented inspection of production equipment following the cleaning; authorization for production to restart following cleaning.
The breakage accident is registered on a proper schedule and an "incident report" is opened with all the details of the line, the CA and the batch of product produced during the breakage.
The records are available and properly analyzed by QC and QAM.

4.9.5 Wood

Wood is well managed according GMP requirement, described in HACCP Manual. Pallets only at the end of the processing lines. Wood use to the minimum.

4.9.6 Other physical contaminants

Procedures are in place to prevent physical contamination of raw materials by raw material packaging (e.g. during debagging and de-boxing procedures to remove the packaging).

Pens used in open product areas are detectable and controlled to minimize the risk of physical contamination (e.g. designed without small parts and detectable by foreign-body detection equipment).

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

After risk assessment, the equipment to detect foreign materials were chosen as follows:

- Filters (250 and 400 µ) are used in 2 steps for filtering the juices for soft drinks production before filling the bottles and (50 µ) for flavouring water. Filter are regularly inspected and properly maintained; Seen record during traceability test.

- last filter 0,5 mm in the filling line (inox) managed as CP.

- Magnet in the glass bottling line to detect missing part of filler as taps or screw and bolts testers are used to verify the detector as described in hazard analysis, managed as CP.

Confirmed by risk analysis reviewed in date 11.12.2017.

4.10.2 Filters and sieves

- Filters (250 and 400 µ) are used in 2 steps for filtering the juices for soft drinks production before filling the bottles and (50 µ) for flavouring water. Filter are regularly inspected and properly maintained; Seen record during traceability test.

- last filter 0,5 mm in the filling line (inox) managed as CP.

4.10.3 Metal detectors and X-ray equipment

After hazard analysis, no MD nor automatic foreign body detector was taken into account, the risk assessment defined monitoring procedure such as magnets (monitored as CP).

Risk assessment dated 11.12.2017.

4.10.4 Magnets

Magnet in the glass bottling line to detect missing part of filler as taps or screw and bolts, testers are used to verify the detector as described in hazard analysis, managed as CP.

Test with Gauss meter.

4.10.5 Optical sorting equipment

Present of inspector on empty and filled bottles checked every start production and every end buy 3 positive sampling

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

Bottles in glass are cleaned with visual inspected.

Magnets in place verified by operator.

Records are available for every production with pressure verification and rising water presence and operating.

4.11 Housekeeping and hygiene

Verified the procedure for Housekeeping and cleaning systems, was definite in accordance at the QMS (ref. 0877 AQ PR 010) and the procedure PRO 7.5.07 “Procedura pulizia e sanificazione” issue 4 dated 10/06/2011 to check the implementation for housekeeping and cleaning of production area, packaging area and storage.
Controls are carried out following IST 7.5.01 VDM “Pulizia impianti di captazione e serbatoi” and on IST 7.5.28 VDM “Igienizzazione sala sciroppi” issue 0. Cleaning registered on MOD 12 VDM “Registro interventi pulizia VDM” issue 1 dated 22/06/2012.
Bioluminescence once a week and registered on MOD 54 VDM “Controlli riempimento” issue 5.
Cleaning is carried out every day and it includes cleaning of equipment, floor and surfaces.
Chemical types and dilution rates available, checks of cleaning carried out with swabs every day.
Cleaning procedures have been developed and verified once a day production manager. Validation carried out yearly with machine manufacturers and have included extensive swabbing programme for TVC.
Seen swab carried out by internal personel with ATP seen record 09.03.2018 conforming result.

4.11.7 Cleaning in place (CIP)

4.11.7 Cleaning in place (CIP)
CIP in place for storage tanks which are cleaned with spray balls and CIP system, as for production lines and pipeline, external part of equipment are manually cleaned by foam device and washed before production start.
Water tank cleaning COP defined in IST 7.5.1 cleaning every 5 year with Divosan Forte and water. Inspection of tanks status done.
Procedure IST 7.5.28 VDM issue 2 dated 22.04.2013 for flavouring area.
CIP is used for sanitizing and cleaning, expected to wash with soda 1,5- 2 % at 80° C, Peracetic acid at 40° C and final rinsing with mineral water, all lines are subject to sanitization with variable frequency, both fillers, mixing room equipment, supply pipes and tanks, both internal and external. Weekly swab for cleaning monitoring of equipment cleaning with bioluminescence control.
Bioluminescence at every CIP, last one dated March 2019 (15.03.2019).
Schematic and validation of the CIP system are available.
Last inspection report on CIP concentration and temperature dated January 2019. Seen record also during traceability records of December 2018.
CIP Validation 20.04.2017 of bottling line and for mixing in 2016.

4.11.8 Environmental monitoring

Eenvironmental monitoring program: swab with bioluminomenter every week and air SAS monthly.
Seen record dated week 11 on silos, pump, hand, sugar equipment, syrup pasteurization, filling machine, conveyor. No research of pathogens but only indicator.

Control limit definition presence of proteins >500, corrective action line re-cleaning and revising of cleaning plan.

The environmental monitoring program is reviewed at least annually during management review.

Seen swab carried out by internal personnel with ATP seen record 14.03.2019 conforming result.
SAS results of last months 11.02.2019 filling area, mixing area, lab and rising machine.

4.12 Waste

The system of waste is adequate: Operative Instruction IST 7.5.193 “Gestione rifiuti” issue 0 available and properly implemented.
Waste collected in designated areas that respect all the standard requirements; was managed in conformity with the local regulations.
Authorized Municipality Company and other qualified ones.
Trade-marked waste are destroyed.

4.13 Management of surplus food and products for animal feed

There is not products surplus for animal feed.

4.14 Pest management

Make clear if there is a contract, or if pest control is undertaken by the site, or partially completed by the site. Ensure that sufficient information is given to determine whether clause 4.13.8 is being complied with. Where a site is seasonal and pest control reflects this – this should be mentioned.
A specific procedure: PRO 7.5.04 VDM “Piano controllo e monitoraggio infestanti” issue 9 is clearly defined in HACCP Manual and in contract with external services company.
A contract with RENTOKILL dated 2012 and yearly renewed was in place with external provider to manage pest control on site 12 routine visits each year. No evidence of infestation was found or had recently been reported. No issues highlighted through trending reports.
The location of all pest control measures is identified in a map of the site 31.01.2019.
The baits are identified. External (using toxic products) and internal baits are used. Specifications and MSDS of pest control products are present (e.g. Rodent). Electrical lamps installed for the insects (mosquitos and flies) catching are correctly sited and they are inspected on a regular basis (every week).
Pheromone traps are present for food insects such as moths, bugs, beetles.
Last intervention dated 14.03.2019 with bait control.
Seen MSDS of product used Eg. Notrak.
In case of identification of pest: replacement of the trap and increase of the checks.
Fly monitored by internal people in date 14.03.2019 (freq. monthly and every 15 days on summer). Fly lamp substitution done annually seen report 03.05.2018.
An in-depth, documented pest control survey is undertaken quarterly, by a pest control expert to review the pest control measures in place: last one carried out on 14.03.2019 done by Landi Rentokil.
Trend analytical half-year.
Monthly inspection, according to the model, it has not identified the other catches.
Last trend in December 2018.
Employees understand the signs of pest activity and are aware of the need to report any evidence of pest activity to a designated manager done in date 15.03.2019.
Measure in place in order to prevent bird (dissuasion placed on incoming area).

4.15 Storage facilities

Storage of raw materials, packaging materials and finish products in dedicated warehouses, segregation of the different types of material is adequate.
There are 3 storage for mineral water tank resin food contact for water stiorage coming from the source, 300 sqm, and 3 tanks in inox 300 sqm. Pipeline connect tanks with bottling lines.
There are 2 cells for storing aromas and juices (0-4 °C and <-18°C). Thermometers are correctly calibrated and checked, with alarm in case of temperature increasing.
The finished products are stable at room temperature and stored in warehouse, external loading area covered.
The stock rotation of raw and packaging materials and finished products is ensure by FIFO criteria and managed by managing system.
No controlled atmosphere.

Stock rotation formula is in place on a first-in first-out basis (FIFO) and inventory turnover ratio is calculated and properly monitored.
Packaging is separately and correctly stored. Some glass packaging materials are stored outside.

4.16 Dispatch and transport

The transport is carried out by several companies chosen by clients and the Operative Instruction 7.5.08 and PRO 7.2.03 “Programmazione della produzione e gestione ordini” specifies the activity.
The HACCP procedure of transport is defined for cleaning monitoring of vehicles level is ensured. A 7 point checklist for vehicles/containers inspection in preloading, loading and closure phases. IST 7.5.08/C “Ispezione container- “Seven Point”.
The temperature control during transport is not required. Checked the temperature of incoming fresh and frozen raw materials as fruit juices and flavours.
Documented maintenance and hygiene procedures maintained for equipment used for loading/unloading.
during audit presence of loading and delivery witnessed by the auditor.

5. Product control

5.1 Product design/development

All new products/processes are submitted to specific R&D procedures including identification and assessment of potential safety hazard: 7.3.01 “Ricerca e Sviluppo” issue 7.
New product: Water flavoured lime. Validated on 24.10.2016, seen shelf life test correctly carried out.
HACCP team approves the new product after validation with legal office, identification of CCPs and validation of the product. Verification of Label conformity made by AQ and client.
The new product documentation is promptly communicated to QA and written in HACCP Manual: Technical Sheets and specification of new product are put into software of the Company.
Seen record of new products development BOBAB HIBISCUS soda organic 750 ml with 2% Juice. Shelf life 40C per 1 months by organoleptic test and cour. PH 3.9 and pasteurized.
Shelf life trials are carried out in case of new products. Records and results from shelf-life tests verified dated 20.09.2018 on Cola 0 BOBAB HIBISCUS soda organic (40C for 30 days).

5.2 Product labelling

Labelling is in line with legal requirements.
During audit the label of product LA GALVANINA lemon FLAVOURED was checked. During traceability: correct label checked on SODA Lemon L 0,750. Privet label WFM
Randomly checked the label of product “MINERAL WATER A” in which ingredients and expiring date are present, Lemonade organic with Sicilian lemon for Baci & B.

No cooking instructions.

5.3 Management of allergens

There is TAB 10 AL “Materie prime contenenti allergeni” issue 0 and PRO 10 “Gestione rischio allergeni” issue 0.

Allergens on site are: None.

Allergen policy on site communicated at induction – staff may not bring allergen containing products on site.
Allergen risk assessment carried out during management review and managed by raw material risk assessment and personnel GMP and training.
All staff is properly trained on purpose: Seen training dated 12.03.2018. Staff folders checked.

5.4 Product authenticity, claims and chain of custody

A complete risk assessment on the vulnerability of each ingredient is carried out by the Company during management review: risk have been determined and correctly avoided through certificates of analysis from raw material suppliers, raw material testing, supply chain audits, mass balance exercises at the raw material supplier.
i Vulnerability assessment of raw materials and packaging has been reviewed annually in date 15.03.2019.

IST 7.5.112 “Gestione delle materie prime biologiche” issue 3 dated 26/1/2011.
Organic certificate by Ecogruppo Italia: ITBIO0081X06/11 expiring on 31.12.2021;
Kosher certificate expiring on 31.05.2019.
Correct Flow of the ingredient and traceability available: seen records of shelf life testing with tasting.
Risk assessment of all product groups has been undertaken in Dec 2017. Full chain traceability checks to source are provided.
Site remains up to date with emerging issues and is able to adapt its system to protect its products against new and existing threats, this is carried out through scientific articles read by QAM and updates carried out by association of category.
Traceability test on organic products performed annually.
No test on Lemo Juice 100% Sicilian

Minor car 2 and 3 of 3

5.5 Product packaging

The packaging that constitutes the unit of sale to the consumer or customer (e.g. bottle, closure and label of a retail pack).

Packaging material used for the final products is:
- Glass bottles. Size: 750ml, 335ml, 1 lt for Glass and 500ml, 1000ml, 1500ml for PET;
- Caps.
- label

Packaging materials were stored and managed in a dedicated area.
The food contact packaging conformity was verified.
Qualified Primary Packaging Suppliers and declaration of conformity verified
The packaging materials are effectively protected after use.
The current specification details the safety use of the packaging material conforming to Reg. 1935/04.
Seen specification for Closure Guala for Glass with food contact conformity dated 02.11.2016.
Glass OI test SSV seen analysis dated with migration test 06.11.2017 and food conformity declaration 06.03.2018.

Storage of all packaging of bottles is outside wile closure and label are store inside.

Packaging materials meet specific legislative requirements in the country that it is to be sold in for the type of packaging, particularly in relation to food contact surfaces.

Procedure to manage obsolete packaging is available.

During the audit verified label and glass bottles on line 2 of mineral water and Lemon soda 355 ml on line 1 L078/19 cod 07002 and Pomegranate cod 07001 and change of products.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

In the Company was present an internal laboratory for microbiological and chemical analyses TAB 7 updated 2018.
The internal lab control plan provides control on raw material as fruit juice, acidifiers, flavours, mineral water for chemical (brix, acidity, heavy metals, conductivity, pH, dry extract and salt contents).
Packaging materials as preforms, caps, bottles and cardboard are controlled for dimension, defects and technical parameters, label are checked for conformity to specific and declarations. Frequency of controls is defined due to sensitiveness of materials, critical limits, responsibility and corrective actions have been defined. Mineral water is analysed at the source every week for microbiological and chemical parameters. Each lot of finished product as mineral water, soft drinks and flavoured MW is daily checked for chemical and microbiological parameters.
The external accredited laboratories CSA Laboratorio (Accredia no 0181), Merieux Nutriscience (Accredia 0051) and Università di Camerino (Accredia no 0863) are in charge for chemical and microbiological determinations (TBC, P. aeruginosa, Coliforms, Streptococci and S. aureus, yeast and moulds) and sensorial analysis.
Seen analysis dated 21.04.2018 lab NSF Internetional accordling to USFDA CFR title 21 part 165.110 on spring galvanina.
Proficiency tests with external Laboratories.

Test results and inspections are recorded and reviewed regularly to identify general trends.
The site has a continuous assessment system of the shelf-life. The system includes the
risk assessment, as well as the microbiological and sensory analysis and the analysis of the relevant chemical factors.

5.6.2 Laboratory testing

Internal lab is segregated from production area and perform only based chemicals and mb analysis (no pathogens analysed). All instrument are calibrated and instruction and methods available and documented.
Seen analysis carried out by internal lab on 11.03.2019 on natural water: confirming results on ph, organoleptic test, cbt, pseudomonas, strept., staph aureus, coliform and clostridia.
Accredited labs: CSA Laboratorio (Accredia no 0181), Merieux Nutriscience (Accredia 0051) and Università di Camerino (Accredia no 0863)
Seen analysis of Università di Camerino dated 13.04.2018 sorgente Galvanina.
Microbiological test of spring water done every 3 months last Lab CSA Accredia 0181 dated 20.12.2018 with Speudomonas aeruginosa 0.
Seen analysis on soft dringks Chinotto Lab Merrieux dated 26.11.2018 on pesticide L187/18. Mb check on Italian Grapefruit Soda L 022219 lab Merieux report dated 12.03.2019. Sampled annually on kind of products.
A system of ongoing shelf-life assessment is in place. Shelf life trials are carried out in case of new products. Records and results from shelf-life tests verified dated 20.09.2018 on Cola 0 BOBAB HIBISCUS soda organic (40C for 30 days).
Test and inspection results are recorded and reviewed regularly to identify trends. The significance of external laboratory results are understood and acted upon accordingly.

Analysis internal on soft drinks 18 and 19/03/2019 on several batch and prodcuts eg. Lemon soda, ph, brix, Co2, assaggio, mould and yeast and stability test 30C per 7days.
More over daily analysis are performed by internal lab.
Ring test carried out on 28.02.2019 on mb and 14.02.2018 for chemicals with Camerino University and 28.02.2018 for chemicals on soda.
The significance of laboratory results are understood and acted by CQ by registering in CQ System.

SAS for air check monthly and swab weekly with ATP.

5.7 Product release

The procedure for laboratory activity was definite in accordance at the QMS
Procedures are in place to ensure that release does not occur until all release criteria have been completed and release authorised.

5.8 Pet Food

NA

6. Process control

6.1 Control of operations

Clear procedures to cover the specific kind of process are in place and well implemented.
PRO 7.2.03 “Programmazione della produzione e gestione ordini logistica” issue 2 on 31/01/11, PRO 7.5.00 “Gestione bottiglie” rev. 1 on03/04/09; PRO 7.5.01 VDM “Ciclo imbottigliamento acqua minerale Val di Meti in PET” issue 3 19/01/11, PRO 7.5.02 VDM “Ciclo imbottigliamento acqua minerale Val di Meti in vetro” issue 3 on 29/04/2011; PRO 7.5.03 VDM “Ciclo di produzione bevande analcoliche in PET” issue 4; PRO 7.5.04 VDM “Ciclo di produzione bevande analcoliche in vetro” issue 3updated on 26/01/12; PRO 7.5.05 VDM “Ciclo di produzione acqua aromatizzata in PET” issue 3; PRO 7.5.06 VDM “Ciclo di produzione acqua mineralizzata in vetro” ver. 8 updated on 16/5/11.
IST 07.05.00 B “Buone pratiche di lavorazione”; IST 7.5.02 “Controlli analitici sciacquatrice”; IST 7.5.30 “Istruzioni per gli operatori alla linea di imbottigliamento”,; TAB 7.5.6 “Piano dei controlli” issue 6.
Verified the daily process parameters checks carried out during flavoring preparation and filling process, as sanitizer presence for cleaning process, absence of sanitizer after final rinsing, pressure of water from nozzles for rinsing, CO2 pressure for carbonated products, filter integrity (50 micron), volume of filed bottle, presence and torque test for caps,

blowing parameters for PET bottles, metal detector checks, label control and coding parameters. All process control are well managed according to QMS and registered
Monitoring of CCPs available and recorded. Equipment settings are completed by authorised trained personnel only.

6.2 Labelling and pack control

Quality Assurance approve the labels. An incoming check of labels and primary packaging is done based on specific plan to check the conformity. During the production, as per point 6.1, the label check is one of the process control.
All products and packaging from the previous production are removed from the line before changing to the next production.
Label checks are documented on production sheet, according to SOP 4015 “Controllo etichette in fase di processo”, issue 1.0.

A new procedure (2022, issue 0.0) was introduced starting from April 2018 in order to ensure the management of new and old basic recipes (BOMs) in the systems for R&D process.

On line verification system (e.g. label code) verified every products change. Seen record during vertical traceability and during the audit from code 072002 to code 072001 on line 1.

6.3 Quantity, weight, volume and number control

Frequency of checks: every batch 80 samples are taken.
Statistical check: every batch.
The frequency of quantity checking is respected on refer Italian legislative requirements DPR 690/78.
The quantity checking was recorded systematically.
Verified the volume check on MOD 229 VDM, using graduated cylinder N LAC – 12B. Seen record of production date 18.03.2019 and 19.03.2019 and during vertical traceability GALVANINA CA EXE SPK MIN W INTERNAL CODE 020600 and soft drink code 072002 Lemon soda Soda 335ml.

6.4 Calibration and control of measuring and monitoring devices

All critical measuring equipment has been calibrated to a National Standard. All the scales are calibrated yearly by accredited external company. The procedure for calibration activity, was definite in accordance at the QMS: 7.6.01 “Procedura per la gestione e la taratura delle apparecchiature” version 4 on 03806/08, in accordance to 7.6 ISO 9001 requirements. Controls are recorded on TAB 7.6.01 “Elenco strumenti di misura con frequenza tarature”, with Calibration Instrument List updated.
Thermometers and weighing scales are calibrated yearly by external authorised contractors.
Calibration was traceable to National standards, with supporting documentation where applicable.
Any issues with measuring and monitoring devices could be raised through non-conformance or corrective action systems.
Seen calibration of balance dated 12B done every 3 months by internal people 18.02.2019 with international samples.
Calibration record manometers 34B done in date 01.09.2018 biannual by Quality Service Lat 135.
Thermometer calibration logger 64B dated 21.07.2017 biannual with primary instruments Tectronic, PT100 43B calibrated annually seen report 28.03.2017 Hendres H. Calibration of pasteurization equipment PT 100 done in date 11.03.2019.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

The procedure for training activity was definite in accordance at the QMS: PRO 6.2.01 “Criteri di addestramento e formazione del personale” version 3 on 26/05/08; training program registred on TAB 6.1.02 “Programma di formazione”.
The training program of assessment and refreshment are approved annually.
Training carried out on :
- Traning on CCP, allergen, food defence and GMP on 15.03.2019 to all operators, by Dr Spinozzi (2h) to 15 operators;
- Training on labelling on 14.03.2019.

For all training effectiveness evaluation was present (test after training).

Detail the site training programme and the competency review that staff undergoes.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

Procedure IST 7.5.00 on 6/6/11 and communicated to the staff. Verified the procedures IST. 7.5.00 “Buone pratiche di igiene e buone pratiche di fabbricazione” and IST 7.5.00 A “Comportamento da tenere in stabilimento per gli appaltatori”.
The hygienic requirements inside the production departments are defined and communicated to the staff.
The Organization defined and documented the hygienic standards for the personnel of manufacturing department. The documents are distributed at the personnel involved.
All cuts and grazes on exposed skin are covered by a coloured blue plasters (no metal detector), and correctly monitored when used by QC (record of checks were available).
No issues seen regarding compliance to documented hygiene policies.
The medicines handling policy is in place and properly applied by the operators: medicines are closed in a locked closet and access is monitored and registered. Used only in case of emergency. The use of personal medicines is well regulated and monitored to avoid the risk of contamination.
No metal check In place.

7.3 Medical screening

Notification by employees regarding infections and similar is properly managed.
Medical screening according to Italian law requirements.
Medical questionnaires were completed by new employees, visitors and contractors.
Illness reporting requirements were suitably detailed and included procedure for action to be taken in event of employers reporting/suffering from infectious disease
Procedures in place whereby staff (or visitors) that are returning to work after illness that maybe/are infectious to prevent them contaminating product.
The medicines handling policy is in place and properly applied by the operators: medicines are closed in a locked closet and access is monitored and registered. Used only in case of emergency.

7.4 Protective clothing: employees or visitors to production areas

Low risk areas is provided Company issued clothing 3 gowns sets, provided to all production staff. Disposable mob hats provided. Safety shoes also provided. Disposable visitor’s coats and hat provided
Protective clothing is removed on leaving the production areas.
Home laundry clothing is protected from home to site with special bags, moreover swabs are carried out in order to validate home laundry (seen swabs carried out on January 2018. No gloves used: seen swabs on clothes and hands dated March 2018 with conforming results.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

The sites do not have High Care or High Risk – Section 8 is Not Applicable

8.2 Building fabric in high-risk and high-care zones

NA

8.3 Maintenance in high-risk and high-care zones

NA

8.4 Staff facilities for high-risk and high-care zones

NA

8.5 Housekeeping and hygiene in the high-risk high-care zones
NA
8.6 Waste/Waste disposal in high risk, high care zones
NA
8.7 Protective clothing in the high-risk high-care zones
NA

Details of non-applicable clauses with justification	
Clause/section reference	**Justification**
3.9.4	No rework used or reworking operations carried out
3.5.4	No outsourced processing and packing
3.5.1.3	No agents or brokers used
4.4.6	No elevated walkways are designed to prevent contamination present
4.10.3.2	No metal detector or X-ray equipment in place
4.10.3.3	No metal detector or X-ray equipment in place
4.10.3.4	No metal detector or X-ray equipment in place
4.10.3.5	No metal detector or X-ray equipment in place
4.13.3	No products intended for animal feed
5.3.5	No rework used or reworking operations carried out
5.3.6	No allergen cross contamination risks
5.3.7	No claims made regarding suitability for allergy or food sensitivity sufferers
5.8	No pet food
6.3.2	No bulk quantities packed

7.2.4	No metal detector in place
7.4.4	No high-risk / high-care areas defined
7.4.5	No high-risk / high-care areas defined

9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

NA

9.2 Specifications

NA

9.3 Product inspection and laboratory testing

NA

9.4 Product legality

NA

9.5 Traceability

NA

IFS Food
Version 6.1

Final Audit Report

Audited company: La Galvanina S.p.A.

Date of audit: 2020-04-27 till 2020-04-29

SGS-International Certification Services GmbH

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Tel +49 (0)40 30.101.361 - Fax +49 (0)40 33.04.098 - www.sgsgroup.de

D-ZE-16090-01-00

IFS Food
Version 6.1, November 2017

Audit Overview

Audit details			
Lead Auditor: Mr. Alfredo Stefani *Co-auditor:* *Trainee(s):*		*Date/time of current audit:* 2020-04-27 (10:00-19:30) 2020-04-28 (09:00-18:30) 2020-04-29 (08:00-12:00)	*Date of previous audit:* 2019-03-20 CB and auditor of previous audit: SGS-International Certification Services GmbH - Bianca Francia
Name and address of the company (or headquarter):		*Name and address of the audited site:* **La Galvanina S.p.A.** Via della Torretta, 2 47923 RIMINI Italy	
		EAN Code/ UCC Global Location Number: COID: 8798	
Phone:	*Fax:*	*Phone:* (+39) 0541 751315	*Fax:* (+39) 0541 752110

Scope of audit	
Exploitation and bottling of mineral water in glass. Production of soft drinks and flavoured water in glass bottles.	
Product scope(s):	8
Technology scope(s):	B, D, E, F

Scopes and processing steps											
		1	2	3	4	5	6	7	8	9	10	11
A	P1	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
B	P2	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐
C	P3	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
C	P4	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
C	P5	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
D	P6	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐
D	P7	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
E	P8	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
E	P9	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
E	P10	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐
F	P11	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐
F	P12	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐
F	P13	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

* The explanation of the product scopes and processing steps are listed separately

Product scopes	Scope description
1	Red and white meat, poultry and meat products
2	Fish and fish products
3	Egg and egg products
4	Dairy products
5	Fruit and vegetables
6	Grain products, cereals, industrial bakery and pastry, confectionary, snacks
7	Combined Products
8	Beverages
9	Oils and fats
10	Dry products, other ingredients and supplements
11	Pet food

Processing step	Processing step description
P1	Sterilisation (e.g. cans)
P2	Thermal pasteurisation, UHT/ aseptic filling; hot filling; Other pasteurisation techniques e.g. high pressure pasteurisation, microwave
P3	Irradiation of food
P4	Preserving: Salting, marinating, sugaring, acidifying/ pickling, curing, smoking, etc. Fermentation/ acidification
P5	Evaporation/ dehydration, vacuum filtration, freeze drying, microfiltration (less than 10 µ mesh size)
P6	Freezing (at least –18 °C) including storage. Quick freezing, Cooling, chilling processes and respective cool storing
P7	Antimicrobial dipping/ spraying, fumigation
P8	Packing MAP, Packing under vacuum
P9	Processes to prevent product contamination esp. microbiological contamination, by means of high hygiene control and/or specific infrastructure during handling, treatment and/or processing e.g. clean room technology, „white room“, controlled working room temperature for food safety purpose, disinfection after cleaning, positive air pressure systems (like filtration below 10µm)
P10	Specific separation techniques: e.g. filtration like reverse osmoses, use of active charcoal
P11	Cooking, baking, bottling, filling of viscous products, brewing, fermentation (e.g. wine), drying, frying, roasting, extrusion, churning
P12	Coating, breading, battering, cutting, slicing, dicing, dismembering, mixing/blending, stuffing, slaughtering, sorting, manipulation, packaging. Storing under controlled conditions (atmosphere) except temperature
P13	Distillation, purification, steaming, damping, hydrogenating, milling

Audit participants					
Name:	**Position:**	**Opening meeting**	**Documenta-tion review**	**Site assessment (Audit)**	**Closing meeting**
Massimo Ambrosini	CEO	☑	☐	☐	☑
Matteo Matassoni	Quality Assurance Manager	☑	☑	☑	☑
Achille Marino	Plants manager	☑	☐	☐	☑
Alfredo Stefani	IFS Auditor	☑	☑	☑	☑
Mauro Bacchini	Production Manager	☐	☐	☑	☐
Marco Musolesi	Warehouse	☐	☐	☑	☐
Roberta De Stefano	QC	☐	☐	☑	☐
Alessandro Carlucci	QC	☐	☐	☑	☐
Lorenzo Valeriani	QC	☐	☐	☑	☐
Marcello Agradi	Purchase	☐	☐	☑	☐
Paolo Catrani	Production Operator	☐	☐	☑	☐
Nicolae Kirita	Production Operator	☐	☐	☑	☐
Michele Frisoni	Production Operator	☐	☐	☑	☐
Emanuele Piaggio	Maintenance	☐	☐	☑	☐

Final result of audit	
As a result of the audit performed from 2020-04-27 till 2020-04-29, „SGS-International Certification Services GmbH“ found that the processing activities of **La Galvanina S.p.A.** for the above mentioned scope of audit comply with the requirements set out in the IFS Food 6.1, Version 6.1, **at Higher Level**, with a score of 99,13%.	**Next audit between 2021-03-04 and 2021-05-13**

Company profile

Product groups and products per group produced in the company:

Product Scope 8
Drinking water - Mineral water
Soft drinks - Soda soft drinks

Description of company / history: The company has been bottling "Galvanina" Mineral Water since 1901, but it is also known as an Ancient Roman Spring. The Company in 2019 was acquired by the American Found Riverside which is now the owner of the company: therefore Family Mini is no longer part of the Company and Matteo Spinozzi is now the site director of Sacramora site and Matteo Matassoni is now the QAM of the group. The company is composed of 3 sites located in Val di Meti, Sacramora Via Popilia Site (open in 2019 where there is the packaging of water and soft drinks in cans and glass) and (the present site) in Rimini.

- Year of construction of the plant: 1967
- Registration number of company: FDA: 10567555272, local authorities: number 304/2007
- GS1 / GLN number: N/A
- COID: 8798
- Last investments concerning quality and safety: New R&D area.
- Emergency contact data: Name: Matteo Marassoni; phone: (+39) 0541 751315; fax: (+39) 0541 752110; email: matteo.matassoni@galvanina.com
- Product groups and products per group: Mineral water in glass, soft drinks and flavoured water in glass. 8 - Beverages
- Overview of processes: The production process consists of pipelines and storage tanks of mineral water, depalletizer for empty bottle visual control before entering the washing equipment for glass bottles, washing, sanitizing and rinser of bottles, filling, capping, control for caps presence, labeling, printing the lot number and expiry date, wrapping or cardboard packer and palletizing. For the preparation of soft drinks dissolvers are used to warm for the ingredients, mixing, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers. P-Step: B-P2: Pasteurization; D-P6: Freezing; E-P10: Filtration; F-P11: Bottling; F-P12: Mixing and Packaging.
- Traded products: N/A
- No. of employees: own employees full time: 45, part time: 0; temporary/leased/flexible employees: 0; no. of shifts: 2
- Seasonal breaks more than one week: two weeks in December
- Outsourced processes: N/A
- Site area in square meters: production area incl. storage: 5500 sqm and including outdoors areas 25.000 sqm.
- Use of IFS logo: The company use the IFS logo in as defined in IFS audit protocol
- Reasons for audit time reduction: N/A
- Other certification: BRC Food, ISO 9001, ISO 14001, ISO 50000, ISO 18001, Kosher, Organic, HACCP
- Exclusions: N/A

Further information: Combination Audit with BRCGS issue 8; no withdrawals nor recalls to date

Reviewer: Joanna Kubica

Audit data	
Outsourced processes and/or products	
Outsourced processes and/or products:	no
Additional audit data	
Total number of employees:	45
Name and contact data (phone, fax, email...) of the contact person in case of emergency:	Matteo Matassoni; phone: (+39) 0541 751315; fax: (+39) 0541 752110; email: matteo.matassoni@galvanina.com
Site area of the plant in square meters:	5500

Explanations regarding the audit report

Evaluation of requirements		
Result	**Explanation**	**Points**
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
KO requirement scored with a B	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	-20 points
Major	When there is a substantial failure to meet the requirements of the Standard, which includes food safety and/or the legal requirements of the production and destination countries. A major can also be given when the identified non-conformity can lead to a serious health hazard. A major can be given to any requirement which is not defined as KO.	15% of the possible total amount of points is subtracted
KO requirement scored with a D	The KO requirement has not been implemented	50 % of the possible total amount of points is subtracted
N/A	Not applicable Requirement not applicable for a company	N/A requirements will be excluded from the final scoring

Scoring and awarding of certificates				
Audit result	**Status**	**Action company**	**Report form**	**Certificate**
At least 1 KO scored with D	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
> 1 Major and/or total score < 75%	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
Max 1 Major and total score ≥ 75%	Not approved unless further actions taken and validated after follow-up audit	Send completed action plan within 2 weeks of receiving the preliminarily report. Follow-up audit max. 6 months after the audit date	Report including action plan gives status	Certificate at foundation level, if the Major non-conformity is finally solved as controlled during the follow-up audit
Total score is ≥ 75 % and < 95%	Approved at foundation IFS Food level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminarily report.	Report including action plan gives status	Yes, certificate at foundation level, 12 months validity
Total score is ≥ 95 %	Approved at higher IFS Food level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminarily report.	Report including action plan gives status	Yes, certificate at higher level, 12 months validity

IFS Food
Version 6.1, November 2017

Audit report

Result:
The processing activities of company „La Galvanina S.p.A.“ met the requirements of the IFS Food, Version 6.1.

The company passed with a score of 99,13% at:

Higher Level

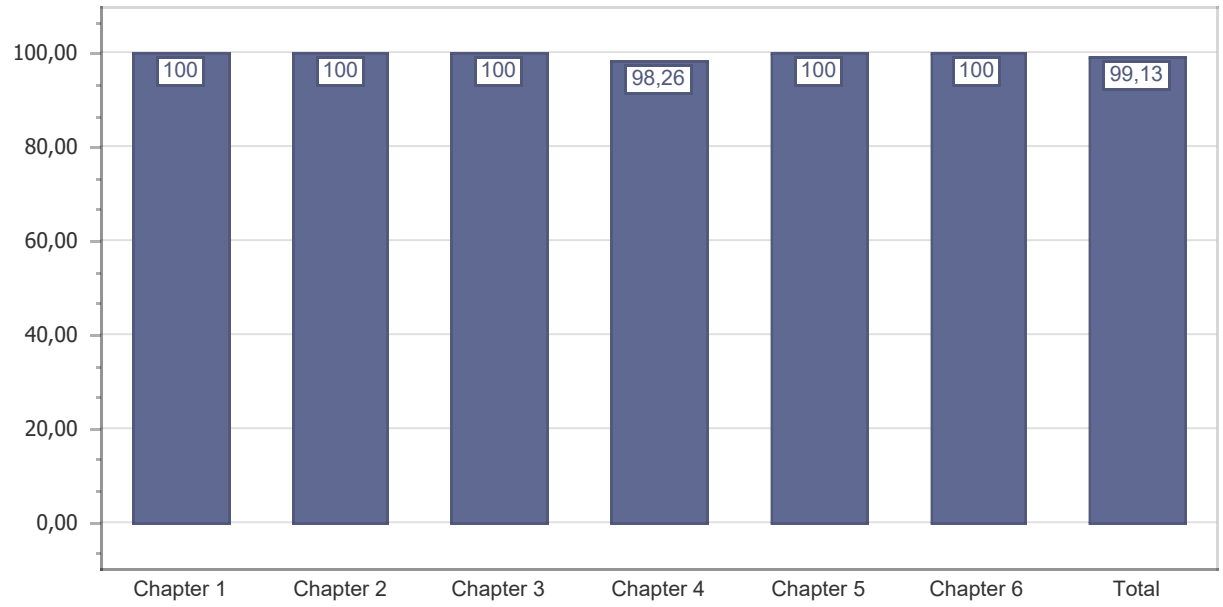
99,13 %

Date of renewal audit: between the 2021-03-04 and the 2021-05-13.

Summary:						
	Chapter 1 Senior management responsibility	Chapter 2 Quality and Food safety management system	Chapter 3 Resource management	Chapter 4 Planning and production process	Chapter 5 Measurements, analyses, improvements	Chapter 6 Food defense
KO	0	0	0	0	0	0
Majors	0	0	0	0	0	0
A	22	33	26	127	42	8
B	0	0	0	1	0	0
C	0	0	0	0	0	0
D	0	0	0	1	0	0
N/A	0	0	2	16	3	0

Observations regarding KO's and Majors:

General summary table for all chapters:



Overall summary of the audit:

Chapter 1: Positive: The organization structure is formalized in Organization charts. Documented procedures are available. The organization structure is formalized. Job descriptions, responsibilities and relevant authorities are clearly defined. The quality objectives and strategies are coherent with the company policy. The resources are adequate and the requires and needs of investments and resources are analyzed during the meetings attended by factory management. Arrangements are defined for key staff absence. Customers' requirements are properly managed. Audits are scheduled according to an annual program which includes Quality, HACCP and IFS Standard, Results of the internal audit are brought to the attention of the personnel responsible for the activity audited. They constitute an input for the improvement of the Quality System. Evidences of improvement plans and corrective actions were seen.
Chapter 1: Negative: No deviation raised

Chapter 2: Positive: The company has implemented a Quality Management System in conformity to UNI EN ISO 9001:2015 and documented in the "Quality Manual. Quality Manual states the company's commitment and covers the requirements of the IFS standard. Operative Procedures and Instructions are present. Documentation is controlled via a formalized document control system. Procedure is in place for documents management and record keeping. Verified list of valid documents. Records are managed in accordance with the Quality System. Collation, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality are properly managed. The retention period for records is defined in max 5 years. A full description of the product is developed and documented in the HACCP Manual, which includes all relevant information on food safety. The flow sheet includes CCPs. All CCPs are under control. The control system is ensured by the QMS document. The HACCP plan prescribes checks for each lot of production. The inquiry involved mainly the hygienically and sanitary risks.
Chapter 2: Negative: No deviation raised

Chapter 3: Positive: Personnel performing work affecting product quality and safety are competent on the basis of appropriate education, training, skills and experience. Training is provided to the staff in accordance with the defined requirements and procedures and results are documented through the relevant plans. All new acquired staff is trained on hygiene and quality. GMP and hygiene rules are correctly applied by staff. The organization's personal hygiene standards are documented and adopted by all personnel, including visitors to the factory. The staff is submitted annually to a medical screening by Company Medicine Service on the basis of the national/regional regulations. Visitors are informed at the entrance on the rules they must follow once they are inside the production areas. The staff

locker rooms are inside to the production building. They are equipped with double partition lockers. The whole staff is aware of the hygienic sanitary standards to be followed in the production departments. Suitable and sufficient hand washing facilities are provided at access and other appropriate points within production areas. Toilets are not opened directly into production area. Toilets are conforming to the standards. Training is adequately managed in accordance with the procedure.
Chapter 3: Negative: No deviation raised

Chapter 4: Positive: The products specifications are detailed for the ingredients and the packaging. The Company has defined an analysis program for validates products shelf life. The company has definite the responsibility and the procedure for the management of the process of purchasing, conforming to requirements. The problems of physical contamination risk is under control by the control of the visual inspection, rinser, bottle inspectors, filters and sieves. There is an effective pest control. Monitoring is made by competent pest control organization. The procedure of housekeeping and hygiene are in place. Record of cleaning are registered in accordance with schedules. There is a system for general traceability. The traceability system is tested yearly since the raw materials. The GMO and allergens problems are taken in mind but actually there are no GMO. No allergens ingredients are managed.
Chapter 4: Negative: 2 deviations highlighted as reported in check list.

Chapter 5: Positive: Internal audits are conducted by qualified personnel. The problems of physical contamination risk is under control by the control of the metal detector device. There is an internal laboratory. The analyses of ingredients and products, are planned and recorded. An analytical plan for products control is available and implemented. Specific chemical analyses are made by external accredited laboratory. Products recall procedure is in place and tested yearly. Processes were closely specified and controlled, according to the requirements of this section. Plant manufacturers had been closely involved at all stages. The controls of processes parameters are methodical and adequate. The responsibilities and methods and the frequency of the control of the process's parameters are defined in the Quality system documents. Corrective action are in place in the case of non conformity.
Chapter 5: Negative: No deviation raised

Chapter 6: Positive: Verified PRO 11.00 "Procedura Food Defence". Team food defence team leader Matteo Spinozzi. Carried out the analysis of possible threats such as contamination of the basins, sabotage along the supply chain, malicious use of the ingredient by the staff. Critical areas identified as saboteurs external suppliers or contractors and internal staff dissatisfaction. System tested with a physical check tested 2 times a year. Site fenced, video cameras, entry codes, with alarm volume in use at the plant and sources connected with internal telephones and Carabinieri, entrance with intercom. Glass bottles with caps with seal to highlight potential openings. Visitors checked and accompanied effectiveness verified with reports from the production staff of drivers entered in the locker room without identification. Verified internal training for staff dedicated to syrups and production operators carried out on 14.03.2019 on food defence, HACCP, GMP, clothing and hygiene standards, with the questionnaire and field monitoring of operators.
Chapter 6: Negative: No deviation raised

Description of follow up of corrective actions from the previous audit:
4.17.1: A new stainless steel cover has been installed before the empty bottles inspector 4.18.4: A new traceability test and mass balance were performed for Products with 100% Sicilian Juice 4.18.5: The testing bottles have been correctly labeled. A new personnel training has been carried out on the correct management of the testing bottles 4.21.2: A traceability test has been commissioned to A. supplier to verify the provenience (SICILY) of the lemon Juice. An accompanying documentation on the provenience (SICILY) of the Sicilian lemon Juice has been requested to the supplier

Chapter 1: Senior management responsibility

Summary of all Chapter 1 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evaluation	Explanation

No non-conformities found.

Chapter 2: Quality and food safety management system

Summary of all Chapter 2 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evaluation	Explanation

No non-conformities found.

Chapter 3: Resource management

Summary of all Chapter 3 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evaluation	Explanation

No non-conformities found.

Chapter 4: Planning and Production Process

Summary of all Chapter 4 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evaluation	Explanation
1	4.10.6	The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.	B	In the “Aroma Area” a rubber hose for water transport is placed on the still floor.
2	4.16.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.	D	On the capping machine for glass bottles, there is a lamp of lubricant fat.

Chapter 5: Measurements, analyses, improvements

Summary of all Chapter 5 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evaluation	Explanation

No non-conformities found.

Chapter 6: Food defense

Summary of all Chapter 6 deviations and non-conformities found:

Nr.	Reference	IFS requirements	Evalua-tion	Explanation

No non-conformities found.

Report of the N/A evaluations

Nr.	Reference	IFS requirements	Evaluation	Explanation
1	3.4.8	Where highly perishable food products are handled, the following additional requirements regarding hand hygiene shall also be provided: - hand contact-free fittings - hand disinfection - adequate hygiene equipment - signage highlighting hand hygiene requirements - waste container with hand contact-free opening.	N/A	No high perishable products
2	3.4.11	Where the hazard analysis and assessment of associated risks show the necessity, cleaning facilities shall be available and used for boots, shoes and further protective clothing.	N/A	Not necessary shoes cleaning facilities, sanitazer carpet at the entrance of production area
3	4.7.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risks shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and food safety.	N/A	No outdoor storage
4	4.8.3	In case of microbiologically sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.	N/A	No microbilogical sensitive area
5	4.9.4.2	Where false ceilings are used, an access to the void shall be provided in order to facilitate cleaning, maintenance and inspections for pest control.	N/A	No false ceilings on site.
6	4.9.8.2	If ventilation equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.	N/A	No forced air equipment installed.

Nr.	Reference	IFS requirements	Evaluation	Explanation
7	4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	N/A	Not present dust extractor
8	4.9.9.2	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	N/A	Not used ricycled water. Present at the factory in a biomass sewage treatment plant for wash water and production waste as juice, with exit water into the environment.
9	4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall not be connected to the drinking water system, or allow the possibility of reflux to contaminate potable water sources or the factory environment.	N/A	There is no use of non-potable water.
10	4.14.6	Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.	N/A	The company doesn't hire a third-party storage service provider.
11	4.15.3	Where goods must be transported at certain temperatures, before loading, the temperature inside the vehicle shall be checked and documented.	N/A	The requirement isn't applicable for products managed at room temperature
12	4.15.4	Where goods must be transported at certain temperatures, maintaining the adequate range of temperatures during transport shall be ensured and documented.	N/A	The requirement isn't applicable for products managed at room temperature

Nr.	Reference	IFS requirements	Evaluation	Explanation
13	4.19.3	There shall be adequate procedures to ensure that where products consisting of or containing GMOs are manufactured, contamination of non-GMO products is avoided. Adequate control measures shall be in place to avoid GMO cross contamination. The effectiveness of these procedures shall be monitored by testing.	N/A	The company doesn't use the products consisting of GMOs, containing GMOs or produced from GMOs.
14	4.19.4	Finished products containing GMOs or labelled as not containing GMOs shall be declared in accordance with current legal requirements. Delivery documents shall include the corresponding reference to GMOs.	N/A	The company doesn't use the products consisting of GMOs, containing GMOs or produced from GMOs.
15	4.19.5	Customer requirements concerning the GMO status of products shall be clearly implemented by the company.	N/A	No customer requirements concerning GMO status of products.
16	4.20.2	Based on hazard analysis and assessment of associated risk, control measures shall be in place from receipt to dispatch, to ensure that cross contamination of products by allergens is minimised. Control measures shall be verified.	N/A	Allergens are not present on site.
17	4.20.3	Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious or unintentional presence, the labelling of legally declared allergens and traces shall be based on hazard analysis and assessment of associated risks.	N/A	Allergens are not present on site.

Nr.	Reference	IFS requirements	Evaluation	Explanation
18	4.20.4	Where customers specifically require that products are “free from” certain substances or ingredients (e.g. gluten, pork, etc.), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.	N/A	Allergens are not present on site.
19	5.3.3	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	N/A	No rework in place
20	5.5.5	For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements for nominal quantity.	N/A	No prepacked products purchased
21	5.10.4	Out of specification, final packaged products or packaging materials, both related to private labels, shall not be placed in the market under the label concerned. Exceptions shall be agreed in writing with the contract partners.	N/A	Out of specification products are destroyed

Detailed audit report

Nr.	Reference	IFS requirements	Evaluation	Explanation
1	1	Senior Management Responsibility		
2	1.1	Corporate policy/Corporate principles		
3	1.1.1	The senior management shall draw up and implement a corporate policy. This shall consider as a minimum: - customer focus - environmental responsibility - sustainability - ethics and personnel responsibility - product requirements (includes: product safety, quality, legality, process and specification). The corporate policy shall be communicated to all employees.	A	
4	1.1.2	The content of the corporate policy shall have been broken down into specific objectives for the related departments. The responsibility and the time scale for achievement shall be defined for each department of the company.	A	
5	1.1.3	From the corporate policy, the quality and food safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented.	A	
6	1.1.4	The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum at least once a year.	A	
7	1.1.5	All relevant information related to food safety and quality shall be communicated effectively and in a timely manner to the relevant personnel.	A	
8	1.2	Corporate structure		

Nr.	Reference	IFS requirements	Evaluation	Explanation
9	1.2.1	An organisation chart shall be available showing the structure of the company.	A	
10	1.2.2	Competences and responsibilities, including deputation of responsibility shall be clearly laid down.	A	
11	1.2.3	Job descriptions with clearly defined responsibilities shall exist and shall be applicable for employees whose work has an effect on product requirements.	A	
12	1.2.4 KO	KO n°1: The senior management shall ensure that employees are aware of their responsibilities related to food safety and quality and that mechanisms are in place to monitor the effectiveness of their operations. Such mechanisms shall be clearly identified and documented.	A	
13	1.2.5	Employees with influence on product requirements shall be aware of their responsibilities, and shall be able to demonstrate their understanding of their responsibilities.	A	
14	1.2.6	The company shall have an IFS representative nominated by senior management.	A	
15	1.2.7	The senior management shall provide sufficient and relevant resources to meet the product requirements.	A	
16	1.2.8	The department responsible for quality and food safety management shall have a direct reporting relationship to the senior management.	A	
17	1.2.9	The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
18	1.2.10	The company shall have a system in place to ensure that it is kept informed of all relevant legislation on food safety and quality issues, scientific and technical developments and industry codes of practice.	A	
19	1.2.11	The company shall inform its customers, as soon as possible, of any issue related to product specification, in particular of all non-conformity (ies) identified by competent authorities related to products which could have, has or has had a defined impact on safety and/or legality of respective products. This could include, but are not limited to cautionary issues.	A	
20	1.3	Customer focus		
21	1.3.1	A documented procedure shall be in place to identify fundamental needs and expectations of customers.	A	
22	1.3.2	The results of this procedure shall be evaluated and considered to determine quality and food safety objectives.	A	
23	1.4	Management review		
24	1.4.1	Senior management shall ensure that the quality and food safety management systems are reviewed at least annually or more frequently if changes occur. Such reviews shall contain, at least, results of audits, customer feedbacks, process compliance and product conformity, status of preventive and corrective actions, follow up actions from previous management reviews, changes that could affect the food safety and quality management systems and recommendations for improvement.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
25	1.4.2	This review shall include the evaluation of measures for the control of the quality and food safety management system and for the continuous improvement process.	A	
26	1.4.3	The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, as a minimum, the following: - buildings - supply systems - machines and equipment - transport. The results of the review shall be considered, with due consideration to risk, for investment planning.	A	
27	1.4.4	The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the work environment needed to achieve conformity to product requirements. This shall include, as a minimum the following: - staff facilities - environmental conditions - hygienic conditions - workplace design - external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to risk for investment planning.	A	
28	2	Quality and Food Safety Management System		
29	2.1	Quality management		
30	2.1.1	Documentation requirements		
31	2.1.1.1	The system for food safety and quality management shall be documented and implemented, and shall be retained in one location (food safety and quality manual or electronic documented system).	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
32	2.1.1.2	A documented procedure shall exist for the control of documents and their amendments.	A	
33	2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	A	
34	2.1.1.4	All documents which are necessary for compliance with the product requirements shall be available in their latest version.	A	
35	2.1.1.5	The reason for any amendments to documents critical for the product requirements shall be recorded.	A	
36	2.1.2	Record keeping		
37	2.1.2.1	All relevant records necessary for the product requirements shall be complete, detailed and maintained and shall be available on request.	A	
38	2.1.2.2	Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.	A	
39	2.1.2.3	All records shall be kept in accordance with legal requirements and for a minimum of one year after the shelf life. For products which have no shelf life, the duration of record keeping shall be justified and this justification shall be documented.	A	
40	2.1.2.4	Any amendments to records shall only be carried out by authorised persons.	A	
41	2.1.2.5	Records shall be securely stored and easily accessible.	A	
42	2.2	Food safety Management		
43	2.2.1	HACCP system		

Nr.	Reference	IFS requirements	Evaluation	Explanation
44	2.2.1.1	The basis of the company's food safety control system shall be a fully implemented, systematic and comprehensive HACCP system, based upon the Codex Alimentarius principles. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The HACCP system shall be implemented at each production site.	A	HACCP Study end Manual PRO 7.5.03 "Sistema di autocontrollo aziendale" last updates (new version17) 07.01.2020. TAB 7.5.07_2 "Piano HACCP mineral water" issue 1 dated 09.01.2019, TAB 7.5.07_1B "Piano HACCP soda" issue 4 dated 14.01.2020 and TAB 7.5.07_A "Piano HACCP flavored water" issue 2 dated 27.01.2020.
45	2.2.1.2	The HACCP system shall cover all raw materials, products or product groups as well as every process from goods into dispatch, including product development and product packaging.	A	
46	2.2.1.3	The company shall ensure that the HACCP system is based upon scientific literature, or technical verified specifications relating to the manufactured products and procedures. This shall be maintained in line with new technical process development.	A	
47	2.2.1.4	HACCP system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any step.	A	
48	2.2.2	HACCP team		
49	2.2.2.1	Assemble HACCP team (CA Step 1) The HACCP team shall be multidisciplinary and include operational staff. Personnel appointed as HACCP team members shall have specific knowledge of HACCP, product and process knowledge and the associated hazards. Where competent knowledge is not available, external expert advice shall be obtained.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
50	2.2.2.2	Those responsible for the development and maintenance of the HACCP system shall have an internal team leader and shall have received adequate training in the application of the HACCP principles.	A	
51	2.2.2.3	The HACCP team shall have strong senior management support and shall be well known and established across the whole facility.	A	
52	2.2.3	HACCP analysis		
53	2.2.3.1	Describe product (CA Step 2) A full description of the product including all relevant information on product safety exists such as: - composition - physical, organoleptic, chemical and microbiological parameters - legal requirements for the food safety of the product - methods of treatment - packaging - durability (shelf life) - conditions for storage, method of transport and distribution.	A	
54	2.2.3.2	Identify intended use (CA Step 3) The intended use of the product shall be described in relation to the expected use of the product by the end consumer, taking into account vulnerable groups of consumers.	A	
55	2.2.3.3	Construct flow diagram (CA Step 4) A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each CCP with the number assigned to it. In the event of any changes the flow diagram shall be updated.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
56	2.2.3.4	On-site confirmation of the flow diagram (CA Step 5) The HACCP team shall verify the flow diagram, by on-site checks, at all operation stages. Amendments to the diagram shall be made, where appropriate.	A	
57	2.2.3.5	Conduct a hazard analysis for each step (CA Step 6 – Principle 1)		
58	2.2.3.5.1	A hazard analysis shall be available for all physical, chemical and biological hazards, including allergens, which may reasonably be expected.	A	
59	2.2.3.5.2	The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects.	A	
60	2.2.3.6	Determine critical control points (CA Step 7 – Principle 2)		
61	2.2.3.6.1	The determination of relevant critical control points (CCP's) shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.	A	
62	2.2.3.6.2	For all steps which are important for food safety, but which are not CCP's, the company shall implement and document control points (CP's) . Appropriate control measures shall be implemented.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
63	2.2.3.7	Establish critical limits for each CCP (CA Step 8 – Principle 3) For each CCP, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.	A	CCPs identified are as follow with relative critical limits: CCP1 – During bottling, physical risk of foreign bodies contamination on empty glass bottles. CA: electronic inspector with cameras. Critical limits: inspector ≥ 2 mm; CCP2 – During bottling in glass, chemical hazard as residues of sanitizer or concentration of sanitizer for cleaning process of degasser and saturator equipment. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water; CCP3 – During bottling at the filling machine, chemical hazard as residues of sanitizer or concentration of rinsing for bottles and rinser equipment cleaning process. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water; CCP4 – During rinsing of bottles, chemical risk of sainting presence. CA: litmus paper. Critical limits: absence of residue of Peracetic acid or concentration or Acid less than 30 ppm in cleaning water; CCP5 – Only for soft drinks During pasteurization of finished product, microbiological hazards for soft drinks, controlled by pasteurization's in tunnel of filled bottles. CA: Pasteurization temperature. Critical limits: 350 PU, min 150 PU, max 900 PU.
64	2.2.3.8	Establish a monitoring system for each CCP (CA Step 9 – Principle 4)		

Nr.	Reference	IFS requirements	Evaluation	Explanation
65	2.2.3.8.1 KO	KO N° 2: Specific monitoring procedures shall be established for each CCP to detect any loss of control at that CCP. Records of monitoring shall be maintained for a relevant period. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records. The records shall specify the person responsible as well as the date and result of the monitoring activities.	A	Monitoring procedure defined as follows: CCP1: Electronic inspector with cameras monitored at start of the line and every hour and at bottles size changing by production staff. Corrective action: if there is a NC parameter the line stops and calibration is repeated until the test is conforming, recorded on MOD 54CCP1_L2; CCP2: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3; CCP3: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3; CCP4: Monitored by production people with litmus test during and at the end of cleaning process, in case of need the sanitization is repeated or rinsing prolonged until absence of sanitizer, recorded on MOD 48 CCP2/3; CCP5: monitored by production staff with data logger for each lot, corrective action block of finished products and evaluation by Quality, organoleptic evaluation carried out, recorded on PC. All records are signed by responsible for the monitoring and verified by an authorized person.
66	2.2.3.8.2	The operative personnel in charge of the monitoring of CCP's shall have received specific training/instruction.	A	
67	2.2.3.8.3	Records of CCP's monitoring shall be checked.	A	
68	2.2.3.8.4	The CP's shall be monitored and this monitoring shall be recorded.	A	
69	2.2.3.9	Establish corrective actions (CA Step 10 – Principle 5) In the event that the monitoring indicates that a particular CCP or CP is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
70	2.2.3.10	Establish verification procedures (CA Step 11 – Principle 6) Procedures of verification shall be established to confirm that the HACCP system is effective. Verification of the HACCP system shall be performed at least once a year. Examples of verification activities include: - internal audits - analysis - sampling - evaluations - complaint by authorities and customers. The results of this verification shall be incorporated into the HACCP system.	A	
71	2.2.3.11	Establish documentation and record keeping (CA Step 12 – Principle 7) Documentation shall be available covering all processes, procedures, control measures and records. Documentation and record keeping shall be appropriate to the nature and size of the company.	A	
72	3	Resource Management		
73	3.1	Human resources management		
74	3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training, commensurate with their role, based on hazard analysis and assessment of associated risks.	A	
75	3.2	Human resources		
76	3.2.1	Personnel hygiene		

Nr.	Reference	IFS requirements	Evaluation	Explanation
77	3.2.1.1	There shall be documented requirements relating to personnel hygiene. These include, as a minimum, the following fields: - protective clothing - hand washing and disinfection - eating and drinking - smoking - actions to be taken in case of cuts or skin abrasions - fingernails, jewellery and personal belongings - hair and beards. The requirements shall be based on hazard analysis and assessment of associated risks in relation to product and process.	A	
78	3.2.1.2 KO	KO N° 3: The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.	A	
79	3.2.1.3	Compliance with personnel hygiene requirements shall be checked regularly.	A	
80	3.2.1.4	Visible jewellery (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and assessment of associated risks in relation to product and process. This shall be effectively managed.	A	
81	3.2.1.5	Cuts and skin abrasions shall be covered by a coloured plaster/bandage (different from the product colour) – containing a metal strip, where appropriate – and in case of hand injuries, in addition to a plaster/bandage, a single use glove shall be worn.	A	
82	3.2.2	Protective clothing for personnel, contractors and visitors		

Nr.	Reference	IFS requirements	Evaluation	Explanation
83	3.2.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing of protective clothing in specified areas in accordance with product requirements.	A	
84	3.2.2.2	In work areas where wearing headgear and/or beard snood (coverings) is required, the hair shall be covered completely, so that product contamination is prevented.	A	
85	3.2.2.3	Clearly defined usage rules shall exist for work areas/activities where it is required to wear gloves (coloured differently from the product colour). Compliance with these rules shall be checked on a regular basis.	A	
86	3.2.2.4	Suitable protective clothing shall be available in sufficient quantity for each employee.	A	
87	3.2.2.5	All protective clothing shall be thoroughly and regularly laundered. Hazard analysis and assessment of associated risks, together with consideration given to the processes and products of the company shall determine if clothing shall be washed by a contract laundry, on site laundry or by the employee.	A	
88	3.2.2.6	Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness.	A	
89	3.2.3	Procedures applicable to infectious diseases		

Nr.	Reference	IFS requirements	Evaluation	Explanation
90	3.2.3.1	There shall be written and communicated measures for personnel, contractors and visitors to declare any infectious disease which may have an impact on food safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.	A	
91	3.3	Training and instruction		
92	3.3.1	The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job and shall include: - training contents - training frequency - employee's task - languages - qualified trainer/tutor - evaluation methodology.	A	
93	3.3.2	The documented training and/or instruction shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training/instruction programs.	A	
94	3.3.3	Records shall be available of all training/instruction events, stating: - list of participants (this shall include their signature) - date - duration - contents of training - name of trainer/tutor. There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
95	3.3.4	The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, food safety, food related legal requirements and product/process modifications.	A	
96	3.4	Sanitary facilities, equipment for personnel hygiene and staff facilities		
97	3.4.1	The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimise food safety risks. Such facilities shall be kept in clean and good condition.	A	
98	3.4.2	The risk of product contamination by foreign material from staff facilities shall be evaluated and minimised. Consideration shall also be given to food brought to work by personnel and personal belongings.	A	
99	3.4.3	There shall be in place rules and facilities to ensure the correct management for personnel belongings and for food brought to work by personnel, food coming from dining room and from vending machines. The food shall only be stored and/or used in designated areas.	A	
100	3.4.4	The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
101	3.4.5	Toilets shall not have direct access to an area where food products are handled. The toilets shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	A	
102	3.4.6	Adequate hand hygiene facilities shall be provided at access points to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risks, further areas (e.g. packaging area) shall be similarly equipped.	A	
103	3.4.7	Hand washing facilities shall provide as a minimum: - running potable water at an appropriate temperature - liquid soap - appropriate equipment for hand drying.	A	.
104	3.4.8	Where highly perishable food products are handled, the following additional requirements regarding hand hygiene shall also be provided: - hand contact-free fittings - hand disinfection - adequate hygiene equipment - signage highlighting hand hygiene requirements - waste container with hand contact-free opening.	N/A	No high perishable products
105	3.4.9	Based on hazard analysis and assessment of associated risks, there shall be a program to control effectiveness of hand hygiene.	A	
106	3.4.10	Changing rooms shall be situated so that they allow direct access to the areas where food products are handled. Based on hazard analysis and assessment of associated risks, exceptions shall be justified and managed.	A	

Nr.	Reference	IFS requirements	Evalua-tion	Explanation
107	3.4.11	Where the hazard analysis and assessment of associated risks show the necessity, cleaning facilities shall be available and used for boots, shoes and further protective clothing.	N/A	Not necessary shoes cleaning facilities, sanitazer carpet at the entrance of production area
108	4	Planning and Production Process		
109	4.1	Contract agreement		
110	4.1.1	The requirements which are defined between the contract partners shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and food safety shall be known and communicated to each relevant department.	A	
111	4.1.2	Changes of existing contractual agreements shall be documented and communicated between the contract partners.	A	
112	4.2	Specifications and formulas		
113	4.2.1	Specifications		
114	4.2.1.1	Specifications shall be available and in place for all finished products. They shall be up to date, unambiguous and be in compliance with legal and customer requirements.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
115	4.2.1.2 KO	KO N° 4: Specifications shall be available and in place for all raw materials (raw materials/ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.	A	PRO 13 “Specifiche di materie prime, imballaggi primari e prodotti finiti” issue 1 dated 10.09.2019. The various kinds of specifications were verified for availability (dedicated files managed according to the rules defined in the Quality Manual). Specifications resulted being updated and available to interested staff. Specifications kept in SW system. Water comes from natural spring "La Galvanina" and there are defined chemical and physical caracteristics defined in order to classifiy water in "Mineral Water" (fixed residues between 500 and 1000 mg/l) following law requirements. The following specification were verified on site: - Colouring agent by Shade Cherry Red dated 17.01.2020; - CO2 by Rivoira dated 03.12.2018; - Citric Acid by Giusto Faravelli dated 01.02.2019; - Concentrated juice by NATEX Ingredients dated 06.02.2019; - Bottle 100cl by VICHY SE TC 26 dated August 2018, declaration of conformity dated 10.01.2019; - Caps by GUALA Closures Group dated 28.08.2019 and declaration of conformity dated 11.02.2020;
116	4.2.1.3	Where required by customers, product specifications shall be formally agreed.	A	Seen specification agreed with clients: - Finished product ALDI American water sparkling mineral 1lt dated 10.01.2020; - Aromatized water AQUA LIME 750ml dated 20.04.2020.
117	4.2.1.4	Specifications and/or their contents shall be provided in the relevant location and accessible to all relevant personnel.	A	
118	4.2.1.5	There shall be a procedure for the creation, the modification and approval of specifications for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications have been agreed with customers.	A	
119	4.2.1.6	The specification control procedure shall include the update of finished product specification in case of any modification: - of raw material - of formula/recipe - of process with influence on the final products - of packaging with influence on the final products.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
120	4.2.2	Formula/recipes		
121	4.2.2.1 KO	KO N° 5: Where there are customer agreements in relation to the product formula/recipe and technological requirements, these shall be complied with.	A	No specific technological requirements and/or formulas are agreed between the contract partners. Anyway data sheet are signed from customer and product complies.
122	4.3	Product development/Product modification/Modification of production processes		
123	4.3.1	A procedure for product development shall be in place which incorporates the hazard analysis principles, in accordance with the HACCP system.	A	
124	4.3.2	Product formulation, manufacturing processes, process parameters and the fulfilment of product requirements shall be established and shall have been assured by factory trials and product testing.	A	
125	4.3.3	Shelf life tests or adequate processes shall be carried out and consideration given to product formulation, packaging, manufacturing and declared conditions; “Use by” or “Best before” dates shall be established accordingly.	A	
126	4.3.4	When establishing and validating the shelf life of the product (including long shelf life product i.e. labelled with a “best before date”), the results of organoleptic tests shall also be taken into account.	A	
127	4.3.5	Product development shall consider the results of organoleptic assessments.	A	
128	4.3.6	A process shall be in place to ensure that labelling complies with current legislation of destination country and customer requirements.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
129	4.3.7	Recommendations for preparation and/or use of the food products shall be established. Where appropriate, customer requirements shall be included.	A	
130	4.3.8	The company shall demonstrate through studies and/or perform relevant tests in order to validate nutritional information or claims which are mentioned on labelling. This applies both for a new product and during all its period of sale.	A	
131	4.3.9	The progress and results of product development shall be properly recorded.	A	
132	4.3.10	The company shall ensure that in the event of changes to product formulation, including rework and packaging material, process characteristics are reviewed in order to assure that product requirements are complied with.	A	
133	4.4	Purchasing		
134	4.4.1	The company shall control purchasing processes to ensure that all externally sourced materials and services, which have an impact on food safety and quality, conform to requirements. Where a company chooses to outsource any process that may have an impact on food safety and quality, the company shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety and quality management system.	A	
135	4.4.2	There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production or part of it.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
136	4.4.3	The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards.	A	
137	4.4.4	The results of suppliers' assessments shall be reviewed regularly and this review shall be based on hazard analysis and assessment of associated risks. There shall be records of the reviews and of the actions taken as a consequence of assessment.	A	
138	4.4.5	The purchased products shall be checked in accordance with the existing specifications and their authenticity, based on hazard analysis and assessment of associated risks. The schedule of these checks shall, as a minimum, take into account the following criteria; product requirements, supplier status (according to its assessment) and impact of the purchased products on the finished product. The origin shall be additionally checked, if mentioned in the specification.	A	
139	4.4.6	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall at least take into account the following items: service requirements, supplier status (according to its assessment) and impact of the service on the finished product.	A	
140	4.5	Product packaging		

Nr.	Reference	IFS requirements	Evaluation	Explanation
141	4.5.1	Based on hazard analysis, assessment of associated risks and intended use, the company shall determine the key parameters for the packaging material.	A	The packaging that constitutes the unit of sale to the consumer or customer (e.g. bottle, closure and label of a retail pack). Packaging material used for the final products is: - Glass bottles. Size: 200ml, 355ml, 750ml and 1lt; - Caps. - Label Packaging materials were stored and managed in a dedicated area. The food contact packaging conformity was verified: - Bottle 100cl by supplier VICHY SE TC 26 specification dated August 2018, declaration of conformity dated 10.01.2019; - Caps by supplier GUALA Closures Group specification dated 28.08.2019 and declaration of conformity dated 11.02.2020; The packaging materials are effectively protected after use. The current specification details the safety use of the packaging material conforming to Reg. 1935/04. Obsolete materials are properly identified and labelled as “Obsolete” and no longer used. Storage of all packaging of bottles is outside wile closure and label are store inside.
142	4.5.2	Detailed specifications shall exist for all packaging materials which comply with the current relevant legislation.	A	
143	4.5.3	For all packaging material which could have an influence on products, certificates of conformity shall exist which comply with current legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging material is suitable for use. This applies for packaging material which could have an influence on raw materials, semi-processed and finished products.	A	
144	4.5.4	Based on hazard analysis and assessment of associated risks, the company shall verify the suitability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis, migration tests).	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
145	4.5.5	The company shall ensure that the packaging used corresponds to the product being packed. The use of correct packaging shall be regularly checked and checks shall be documented.	A	
146	4.5.6	Labelling information shall be legible indelible and shall comply with agreed customer product specifications. This shall be regularly checked and checks shall be documented.	A	
147	4.6	Factory location		
148	4.6.1	The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. Where it is established product safety and quality could be compromised, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells).	A	
149	4.7	Factory Exterior		
150	4.7.1	The factory exterior shall be maintained to be clean and tidy.	A	
151	4.7.2	All external areas of the factory shall be maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.	A	
152	4.7.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risks shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and food safety.	N/A	No outdoor storage
153	4.8	Plant layout and process flows		

Nr.	Reference	IFS requirements	Evaluation	Explanation
154	4.8.1	Plans clearly describing internal flows of finished products, packaging materials, raw materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available.	A	
155	4.8.2	The process flow, from receipt of goods to dispatch, shall be in place so that contamination of raw materials, packaging, semi-processed and finished products is avoided. The risk of cross-contamination shall be minimised through effective measures.	A	
156	4.8.3	In case of microbiologically sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.	N/A	No microbilogical sensitive area
157	4.8.4	Laboratory facilities and in-process controls shall not affect the product safety.	A	
158	4.9	Constructional requirements for production and storage areas		
159	4.9.1	Constructional requirements		
160	4.9.1.1	Rooms where food products are prepared, treated, processed and stored shall be designed and constructed so that food safety is ensured.	A	
161	4.9.2	Walls		
162	4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning.	A	
163	4.9.2.2	The surfaces of walls shall be in a good condition and easy to clean; they shall be impervious and wear-resistant.	A	
164	4.9.2.3	The junctions between walls, floors and ceilings shall be designed to facilitate cleaning.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
165	4.9.3	Floors		
166	4.9.3.1	Floor covering shall be designed to meet production requirements and shall be in good condition and easy to clean. Surfaces shall be impervious and wear-resistant.	A	
167	4.9.3.2	The hygienic disposal of waste water shall be ensured. Drainage systems shall be easy to clean and designed to minimise the risk of product contamination (e.g. ingress of pests, etc.).	A	
168	4.9.3.3	Water or other liquids shall reach drainage without difficulties, using appropriate measures. Puddles shall be avoided.	A	
169	4.9.3.4	In food handling areas, machinery and piping shall be arranged so that waste water, if possible, goes directly into a drain.	A	
170	4.9.4	Ceilings/Overheads		
171	4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (incl. piping, cableway, lamps etc.) shall be constructed to minimise the accumulation of dirt and shall not pose any risk of physical and/or microbiological contamination.	A	
172	4.9.4.2	Where false ceilings are used, an access to the void shall be provided in order to facilitate cleaning, maintenance and inspections for pest control.	N/A	No false ceilings on site.
173	4.9.5	Windows and other openings		
174	4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
175	4.9.5.2	Where there is risk of contamination, windows and roof glazing shall remain closed and fixed during production.	A	
176	4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easily removable, good condition pest screens or other measures in order to avoid any contamination.	A	
177	4.9.5.4	In areas where unpackaged product is handled, windows shall be protected against breakage.	A	
178	4.9.6	Doors and gates		
179	4.9.6.1	Doors and gates shall be in good condition (e.g. no splintering parts, flaking paints or corrosion) and easy to clean.	A	
180	4.9.6.2	External doors and gates shall be constructed to prevent the ingress of pests; if possible, they shall be self-closing.	A	
181	4.9.7	Lighting		
182	4.9.7.1	All working areas shall have adequate lighting.	A	
183	4.9.7.2	All lighting equipment shall be protected by shatter proof covers and installed to minimise the risk of breakage.	A	
184	4.9.8	Air conditioning/Ventilation		
185	4.9.8.1	Adequate natural and/or artificial ventilation shall exist in all areas.	A	
186	4.9.8.2	If ventilation equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.	N/A	No forced air equipment installed.
187	4.9.8.3	Air conditioning equipment and artificially generated airflow shall not lead to any product safety or quality risks.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
188	4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	N/A	Not present dust extractor
189	4.9.9	Water supply		
190	4.9.9.1	Water which is used as ingredient in the production process, or for cleaning, shall be of potable quality and supplied in sufficient quantity; this also applies to steam and ice used within the production area. A supply of potable water shall be available at all times.	A	Procedure for water management in HACCP manual Potable water in use available from spring source. Schematic plant of water issue 01 dated 07.01.2019. Relevant records are maintained. Pluming system map detailing all sampling points was available. Plan of control is defined TAB 7.5.06 “Piano dei Controlli” issue 25 dated 19.08.2019: Water is tested every year for microbiological (including TMC, E.Coli, Coliforms and Enterococcus) and chemical (including heavy metals) parameters with reference to Circolare 17 dated 1991, DM 10.02.2015 and DL 08.10.2011 and to D. Lgs. 31/2001. Analysis are carried out_ - by external accredited (micro and chemical) lab Università di Camerino (Accredia 8663L),seen report with conforming results dated 10.04.2020 and 05.03.2020; - Internally weekly check done by internal lab seen record of February and March 2020; - Microbiological test of spring water done every 4 months by Lab CSA (Accredia 0181L) last one dated 20.12.2019 with Speudomonas aeruginosa 0.
191	4.9.9.2	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	N/A	Not used ricycled water. Present at the factory in a biomass sewage treatment plant for wash water and production waste as juice, with exit water into the environment.
192	4.9.9.3	The quality of water, steam or ice shall be monitored following a risk based sampling plan.	A	
193	4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall not be connected to the drinking water system, or allow the possibility of reflux to contaminate potable water sources or the factory environment.	N/A	There is no use of non-potable water.
194	4.9.10	Compressed air		

Nr.	Reference	IFS requirements	Evaluation	Explanation
195	4.9.10.1	The quality of compressed air that comes in direct contact with food or primary packaging material shall be monitored based on hazard analysis and assessment of associated risks.	A	
196	4.9.10.2	Compressed air shall not pose a risk of contamination.	A	
197	4.10	Cleaning and disinfection		
198	4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: - objectives - responsibilities - the products used and their instructions for use - the areas to be cleaned and/or disinfected - cleaning frequency - documentation requirements - hazard symbols (if necessary).	A	
199	4.10.2	Cleaning and disinfection schedules shall be implemented and documented.	A	
200	4.10.3	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.	A	
201	4.10.4	The effectiveness and safety of the cleaning and disinfection measures, based on hazard analysis and assessment of associated risks, shall be verified and documented according to a sampling schedule by using appropriate procedures. Resultant corrective actions shall be documented.	A	
202	4.10.5	Cleaning and disinfection schedules shall be reviewed and modified, if necessary, in the event of a change to product, process or cleaning equipment.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
203	4.10.6	The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.	B	In the “Aroma Area” a rubber hose for water transport is placed on the still floor.
204	4.10.7	Current safety data sheets (SDS) and instructions for use shall be available for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions, which shall be always available on site.	A	
205	4.10.8	Cleaning chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination.	A	
206	4.10.9	Cleaning activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled as to not affect the product.	A	
207	4.10.10	Where a company hires a third -party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the respective contract.	A	
208	4.11	Waste disposal		
209	4.11.1	A waste management procedure shall exist and shall be implemented to avoid cross contamination.	A	
210	4.11.2	All current legal requirements for waste disposal shall be met.	A	
211	4.11.3	Food waste and other waste shall be removed as quickly as possible from areas where food is handled. The accumulation of waste shall be avoided.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
212	4.11.4	Waste collection containers shall be clearly marked, suitably designed, in good state of repair, easy to clean, and where necessary disinfected.	A	
213	4.11.5	Waste collection rooms and containers (incl. compactors) shall be designed to be kept clean to minimise pest attraction.	A	
214	4.11.6	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorised third parties only. Records of waste disposal shall be kept by the company.	A	
215	4.12	Risk of foreign material, metal, broken glass and wood		
216	4.12.1 KO	KO N° 6 Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign material. Contaminated products shall be treated as non-conforming products.	A	After risk assessment, the equipment to detect foreign materials were chosen as follows: - Filters (250 and 400 µ) are used in 2 steps for filtering the juices for soft drinks production before filling the bottles and (50 µ) for flavouring water. Filter are regularly inspected and properly maintained; Seen record during traceability test. Last filter 0,5 mm in the filling line (inox) managed as CP. - Magnet in the glass bottling line to detect missing part of filler as taps or screw and bolts testers are used to verify the detector as described in hazard analysis, managed as CP. - Optical Sorting Equipment: IST 7.5.04 “Gestione Ispezionatrice Heuft VX” Rev. 0 of 18/01/2016. Present of inspector on empty and filled bottles checked every start production and every end buy 3 positive sampling. For the soda line TAB. 7.5.07_1B “Soda HACCP plan” Rev. 4 of 14/01/2020 describes the corrective actions and reporting procedures in case of failure of the empty bottles optical inspection machine. After hazard analysis, no MD nor automatic foreign body detector was taken into account, the risk assessment defined monitoring procedure such as magnets (monitored as CP).

Nr.	Reference	IFS requirements	Evaluation	Explanation
217	4.12.2	In all areas, e.g. handling of raw materias, processing, packing and storage, where hazard analysis and assessment of associated risks have identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled and the wood shall be in good order and clean.	A	
218	4.12.3	Where metal- and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection, in order to avoid subsequent contamination. Detectors shall be subjected to regular maintenance to avoid malfunction.	A	
219	4.12.4	Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.	A	
220	4.12.5	The appropriate accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of a metal and/or foreign material detector, corrective actions shall be defined, implemented and documented.	A	
221	4.12.6	In cases where special equipment or methods are used to detect foreign material, these shall be properly validated and maintained.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
222	4.12.7	In all areas, e.g. handling of raw materials, processing, packing and storage, where hazard analysis and assessment of associated risks have identified a potential product contamination, the presence of glass and brittle material shall be excluded. Where the presence of glass or brittle plastic cannot be avoided, appropriate measures shall be in place to protect against breakage.	A	
223	4.12.8	All stationary objects made of or incorporating glass or brittle material present in areas of handling of raw materials, processing, packing and storage shall be listed in a specific register, including details of their exact location. An assessment of the condition of objects on the register shall be performed on a regular basis and recorded. Frequency of this check shall be justified by documents.	A	
224	4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	A	
225	4.12.10	Procedures shall be in place describing the measures to be taken in case of breakage of glass and/or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and release of production line for continued production.	A	
226	4.12.11	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for handling of glass packaging, glass containers or other kinds of containers in the production process (turn over, blow, rinse, etc.). After this process step there shall be no further risk of contamination.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
227	4.12.12	Where visual inspection is used to detect foreign material, the employees shall be trained and operative change shall be performed at an appropriate frequency to maximise effectiveness of process.	A	
228	4.13	Pest monitoring/Pest control		
229	4.13.1	The company shall have a pest control system in place which is in compliance with local legal requirements, taking into account, as a minimum: - the factory environment (potential pests) - site plan with area for application (bait map) - identification of the baits on site - responsibilities, in-house/external - used products/agents and their instructions for use and safety - the frequency of inspections. The pest control system shall be based on hazard analysis and assessment of associated risks.	A	A specific procedure: PRO. 7.5.04 “Controllo e monitoraggio degli infestanti” Rev. 11 of 06/02/19 is clearly defined in HACCP Manual and in contract with external services company. A contract with RENTOKILL dated 2012 and yearly renewed was in place with external provider to manage pest control on site 12 routine visits each year. No evidence of infestation was found or had recently been reported. No issues highlighted through trending reports. The location of all pest control measures is identified in a map of the site 31.01.2019. External (using toxic products) and internal baits are used. Electrical lamps installed for the insects (mosquitos and flies) catching are correctly sited and they are inspected on a regular basis (every week). Pheromone traps are present for food insects such as moths, bugs, beetles. The site has adequate measures to prevent birds from entering buildings or roosting above loading or unloading areas, (nets and obstacles), seen report of birds absence dated 21.06.2019. Last intervention dated 10.04.2020 with bait control and product used Ratkill Blox (MSDS issue 1 dated December 2014). Fly monitored by internal people (freq. monthly and every 15 days on summer). Fly lamp substitution done annually seen report 16.04.2020. An in-depth, documented pest control survey is undertaken quarterly, by a pest control expert to review the pest control measures in place: last one carried out on 23.04.2020 done by Landi Rentokil. Employees understand the signs of pest activity and are aware of the need to report any evidence of pest activity to a designated manager done in date 21.05.2018 (4h) by Matteo Matassoni to 2 operators (Alessandro Carlucci and Samuele Donati)..
230	4.13.2	The company shall have qualified and trained in-house staff and/or employ the services of a qualified external provider. Where an external provider is used, the activities required on site shall be specified in a written contract.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
231	4.13.3	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.	A	
232	4.13.4	Baits, traps and insect exterminators shall be functioning, shall be in sufficient numbers and shall be placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination risk.	A	
233	4.13.5	Incoming deliveries shall be checked on arrival for the presence of pests. Any infestation shall be documented and control measures taken.	A	
234	4.13.6	The effectiveness of the pest control shall be monitored with the help of regular trend analyses.	A	
235	4.14	Receipt of goods and storage		
236	4.14.1	All incoming goods, including packaging materials and labels, shall be checked for conformity against specifications and to a determined inspection plan. The inspection plan shall be risk based. Test results shall be documented.	A	
237	4.14.2	The storage conditions of raw materials, semi-processed and finished products as well as packaging shall in each case correspond to product requirements (e.g. refrigeration, protective covers) and shall not be detrimental to other products.	A	
238	4.14.3	Raw materials, packaging, semi-processed and finished products shall be stored so as to minimise the risk of cross contamination.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
239	4.14.4	Appropriate storage facilities shall be available for the management and storage of working materials, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.	A	
240	4.14.5	All products shall be clearly identified. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out.	A	
241	4.14.6	Where a company hires a third -party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.	N/A	The company doesn't hire a third-party storage service provider.
242	4.15	Transport		
243	4.15.1	Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, pests, mould) shall be checked and action taken, if necessary.	A	
244	4.15.2	Procedures to prevent contamination during transport shall be implemented (food/non-food/different categories of goods).	A	
245	4.15.3	Where goods must be transported at certain temperatures, before loading, the temperature inside the vehicle shall be checked and documented.	N/A	The requirement isn't applicable for products managed at room temperature
246	4.15.4	Where goods must be transported at certain temperatures, maintaining the adequate range of temperatures during transport shall be ensured and documented.	N/A	The requirement isn't applicable for products managed at room temperature

Nr.	Reference	IFS requirements	Evaluation	Explanation
247	4.15.5	Adequate hygienic requirements for all transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) shall exist. There shall be records of the measures taken.	A	
248	4.15.6	Loading and unloading areas shall have equipment in place to protect transported products from external influences.	A	
249	4.15.7	Where a company hires a third -party transport service provider, all the requirements specified within section 4.15 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.	A	
250	4.15.8	Security of transport vehicles shall be appropriately maintained.	A	
251	4.16	Maintenance and repair		
252	4.16.1	An adequate system of maintenance shall be in place, maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.	A	
253	4.16.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.	D	On the capping machine for glass bottles, there is a lamp of lubricant fat.
254	4.16.3	All materials used for maintenance and repair shall be fit for the intended use.	A	
255	4.16.4	Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed with a view to adapting the maintenance system.	A	

Nr.	Reference	IFS requirements	Evalua-tion	Explanation
256	4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented and a short-term deadline set for eliminating the fault.	A	
257	4.16.6	Where a company hires a third -party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained.	A	
258	4.17	Equipment		
259	4.17.1	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.	A	
260	4.17.2	For all equipment and tools with direct food contact, certificates of conformity shall exist which confirm compliance with current legal requirements. In case no specific legal requirements are applicable, evidence shall be available to demonstrate that all equipment and tools are suitable for use. This applies for all equipment and tools in direct contact with raw materials, semi-processed and finished products.	A	
261	4.17.3	Equipment shall be designed and located so that cleaning and maintenance operations can be effectively performed.	A	
262	4.17.4	The company shall ensure that all product equipment is in good condition without any negative influence on food safety.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
263	4.17.5	The company shall ensure that in the event of changes to processing methods and equipment, process characteristics are reviewed in order to assure that product requirements are complied with.	A	
264	4.18	Traceability (including GMOs and allergens)		
265	4.18.1 KO	KO N° 7: A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with food, packaging intended or expected to be in direct contact with food. The traceability system shall incorporate all relevant receiving processing and distribution records. Traceability shall be ensured and documented until delivery to the customer.	A	During the audit the process was testes on finished product Sparkling Limeade French Style (Safeway) production date 14.01.2020, batch 14012022 expiring on 14.01.2022. Seen recipe of the product with batches of raw materials at the pc. Seen production order dated 14.01.2020 with CO2 used (5,6-6,0g) batch 50419, bottles and caps batch 40108. Seen label and technical sheet of raw material. Seen certificate of analysis Tate & Lyle dated 03.12.2019 with conforming results. Seen analysis with conforming results dated 27.06.2019 on Aroma Kerry, 29.04.2019 on citric acid, 14.01.2020 on finished product. Seen ok for pasteurization. Time: 1,5h.
266	4.18.2	Downstream traceability records (from production sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements.	A	
267	4.18.3	Traceability shall be in place to identify the relationship between batches of final products and their labels.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
268	4.18.4	The traceability system shall be tested on a periodic basis - at least annually and each time traceability system changes. The test shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa), including quantity checking. Test results shall be recorded.	A	A traceability test was conducted by the Company on 26.02.2020 from finished product ORGANIC SODA TANGERI WFM 750ml batch TB050A2000L1. From the batch number it is possible to trace back to the date of production (MOD. 78 production order of the 19.02.2020). From the production date back to the warehouse discharges (see stock brogliaccio print), relating to packaging carbon dioxide,…: - bottles lot O14320047 / 20, q discharged 76.142, q, used 38,100. Internal Inspection Checklist Mod. 01CBI Rev. 7 of 04/02/2020 p. 16 of p. 20; - lot caps 190405005P, q discharged 171.924, q used 38,100; - carbon dioxide lot C042080520, q discharged 1085 Kg, q used 171.45 Kg. The ingredients of the recipe are listed in the leaflet production extracted from management: n. 400 of 17/02/2020 e 19/02/2020 in which the warehouse discharges are indicated of the ingredients: Eg. Giotti Citrusol Mandarin Essence L2018, q discharged 1.118 Kg, q used 1.118 Kg. From these data back to Ddt of raw materials and ingredients used: es. GIOTTI v. DdT n. 2019/5009 of 23/05/2019 downstream traceability: printout of the management software with list of delivery documents product. Final balance of the finished product: 38,100 bottles produced, q 3,468 still in stock, q sold 34,632. Time: 3h. Seen another test dated 26.02.2020 from raw material Natural Aroma Mulberry by supplier Sensient vatch 1920623909 purchased on 31.07.3019 (25kg) expiring on 28.02.2020. Seen the used of the 25kg 4 times (production dated 20.08.2019, 09.09.2019, 11.11.2019 and 20.01.2020): residual 17,221kg. Time 30 minutes.
269	4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
270	4.18.6	Labelling of semi-finished or finished product lots shall be made at the time when the goods are directly packed to ensure a clear traceability of goods. Where goods are labelled at a later time, the temporarily stored goods shall have been provided with a specific lot labelling. The shelf life (e.g. best before date) of the labelled goods shall be calculated from the original production batch.	A	
271	4.18.7	If required by customer, identified samples representative for the manufacturing lot shall be stored appropriately and kept until expiration of the “Use by” or “Best before date” of the finished product and if necessary for a determined period beyond this date.	A	
272	4.19	Genetically modified organisms (GMOs)		
273	4.19.1	For products being delivered to customers and/or countries with GMO requirements, the company shall have in place systems and procedures to allow the identification of products consisting of GMOs, containing GMOs or produced from GMOs, including food ingredients, additives and flavouring(s).	A	Is the company working with products consisting of GMOs, containing GMOs or produced from GMOs? : no The company doesn't use the products consisting of GMOs, containing GMOs or produced from GMOs. IST 7.5.112 “Gestione delle materie prime biologiche” issue 03 for managing different kind of soft drinks are organic and this activity is managed and registered in the dedicated procedure and monitored by external certification body every 3 months, with in-out mass balance, check of labels and warehouse inventory with mass balance matches. Verified organic certification by Ecogruppo Italia with mass balance.

Nr.	Reference	IFS requirements	Evaluation	Explanation
274	4.19.2	Raw material specifications and delivery documents identifying products consisting of, being made from, or containing GMOs shall be available. The assurances concerning the GMO status of the raw materials shall be agreed by contract with the supplier or the relevant technical documents shall specify the GMO status. The company shall maintain a continuously updated listing of all GMO raw materials used at its premises, which also identifies all blends and formulas to which such GMO raw materials are added.	A	The Company does not label product as "GMO-free". GMO status of raw materials verified, agreed by contract and specification, specifying the NON-GMO status. No GMOs processed.
275	4.19.3	There shall be adequate procedures to ensure that where products consisting of or containing GMOs are manufactured, contamination of non-GMO products is avoided. Adequate control measures shall be in place to avoid GMO cross contamination. The effectiveness of these procedures shall be monitored by testing.	N/A	The company doesn't use the products consisting of GMOs, containing GMOs or produced from GMOs.
276	4.19.4	Finished products containing GMOs or labelled as not containing GMOs shall be declared in accordance with current legal requirements. Delivery documents shall include the corresponding reference to GMOs.	N/A	The company doesn't use the products consisting of GMOs, containing GMOs or produced from GMOs.
277	4.19.5	Customer requirements concerning the GMO status of products shall be clearly implemented by the company.	N/A	No customer requirements concerning GMO status of products.
278	4.20	Allergens and specific conditions of production		

Nr.	Reference	IFS requirements	Evaluation	Explanation
279	4.20.1	Raw material specifications identifying allergens requiring declaration that are relevant to the country of sale of the finished product shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added.	A	PRO 10 “Gestione rischio allergeni” issue 0. No Allergens are used in production processes. A training is carried out on Personnel to avoid potential gluten contamination coming after break-time during which products brought by personnel with allergens that could contains allergens.
280	4.20.2	Based on hazard analysis and assessment of associated risk, control measures shall be in place from receipt to dispatch, to ensure that cross contamination of products by allergens is minimised. Control measures shall be verified.	N/A	Allergens are not present on site.
281	4.20.3	Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious or unintentional presence, the labelling of legally declared allergens and traces shall be based on hazard analysis and assessment of associated risks.	N/A	Allergens are not present on site.
282	4.20.4	Where customers specifically require that products are “free from” certain substances or ingredients (e.g. gluten, pork, etc.), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.	N/A	Allergens are not present on site.
283	4.21	Food Fraud		

Nr.	Reference	IFS requirements	Evaluation	Explanation
284	4.21.1	A documented food fraud vulnerability assessment shall be undertaken on all raw materials, ingredients, packaging and outsourced processes, to determine the risk of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined.	A	Fraud-susceptible raw materials/products identified in the vulnerability assessment: Organic foods Which one(s) Juice, sugar and flovours Certain fruit juices Which one(s) Citron juice PRO. 14 “Valutazione della vulnerabilità sull'autenticità del prodotto” Rev. 1 of 02/09/2019 and TAB. 14 “Valutazione della vulnerabilità alla sofisticazione/sostituzione delle materie prime e imballaggi primari” Rev. 1 of 02/09/2019. A complete risk assessment on the vulnerability of each ingredient is carried out by the Company during management review: risk have been determined and correctly avoided through certificates of analysis from raw material suppliers, raw material testing, supply chain audits, mass balance exercises at the raw material supplier. Red Orange and other organic raw material could not be organic or not from Sicily: certificate are required at every arrival, following IST 7.5.112 “Gestione delle materie prime biologiche” issue 3 dated 26/1/2011. Economics factors: those raw materials could be substituted with lower quality or non-organic ones.
285	4.21.2	A documented food fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.	A	
286	4.21.3	In the event of increased risk, food fraud vulnerability assessment shall be reviewed. Otherwise all vulnerability assessments shall be reviewed at least annually. Control and monitoring requirements of the food fraud mitigation plan shall be reviewed and amended when applicable.	A	
287	5	Measurements, Analysis, Improvements		
288	5.1	Internal audits		

Nr.	Reference	IFS requirements	Evaluation	Explanation
289	5.1.1 KO	KO N° 8: Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS Standard. Scope and frequency of internal audits shall be determined by hazard analysis and assessment of associated risks. This is also applicable for off-site storage locations owned or rented by the company.	A	
290	5.1.2	Internal audits of activities which are critical to food safety and product specifications shall be carried out at least once a year.	A	In the site, all areas are defined critical to food safety and to product specifications and therefore are periodically object of internal audits. Seen records of audits all carried out by external consultant Rita Barbieri dated: - 04.03.2019 on Std BRC p. 1 IFS p. 1-2, Std BRC p. 3, 3.1, 3.2, 3.3, 3.4, 3.9, IFS p. 2-4.18-5.1. One observation raised for the procedure of documents management; - 28.06.2019 on Std BRC p. 4.11-4.16-; STD IFS p. 4.10, 4.11, 4.13, 4.14, 4.15 and Std BRC p. 5, STD IFS p. 4.3, 4.5, 4.20, 4.21, 4.15, 5.6. One observation for the procedure PRO14 to be update; - 25.09.2019 on Std BRC p. 6-; STD IFS p. 4 and Std BRC p. 7 STD IFS p. 3. One observation raised; - 28.02.2020 on Std BRC p. 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, STD IFS p. 2-4. Two observations raised on IT procedure for doc management. Corrective actions are in place in case of non-conformity.
291	5.1.3	The auditors shall be competent and independent from the audited department.	A	
292	5.1.4	Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined and documented and communicated to every relevant person.	A	
293	5.1.5	It shall be documented how and when the corrective actions resulting from the internal audits shall be verified.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
294	5.2	Site factory inspections		
295	5.2.1	Factory inspections shall be planned and carried out (e.g. product control, hygiene, foreign material hazards, personnel hygiene and housekeeping). The frequency of inspections in every area (including outdoor areas) and every single activity shall be based on hazard analysis and assessment of associated risks and on the history of previous experience.	A	
296	5.3	Process validation and control		
297	5.3.1	The criteria for process validation and control shall be clearly defined.	A	
298	5.3.2	In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties etc.) is essential to ensure the product requirements, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.	A	
299	5.3.3	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	N/A	No rework in place
300	5.3.4	There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.	A	
301	5.3.5	Process validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a revalidation shall be carried out.	A	
302	5.4	Calibration, adjustment and checking of measuring and monitoring devices		

Nr.	Reference	IFS requirements	Evaluation	Explanation
303	5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be recorded on a document and clearly identified.	A	
304	5.4.2	All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognised standard/methods. The results of the checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and, if necessary, on process and products shall be carried out.	A	
305	5.4.3	All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements indicate a malfunction, the device in question shall be immediately repaired or replaced.	A	
306	5.4.4	The calibration status of the measuring devices shall be clearly identified (labelling at the machine or on a list of test devices).	A	
307	5.5	Quantity checking (quantity control/filling quantities)		
308	5.5.1	The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if appropriate, guidelines for nominal quantity are met.	A	PRO. 11.01 “Analisi Fisica CAPACITA’ VOLUMETRICA” Rev. 1 of 03/09/2019. Verified the volume check on MOD 229 VDM, using graduated cylinder N LAC – 12B. Frequency of checks: every batch 20 samples are taken. Statistical check: every batch. The frequency of quantity checking is respected on refer Italian legislative requirements DPR 690/78. The quantity checking was recorded systematically.

Nr.	Reference	IFS requirements	Evaluation	Explanation
309	5.5.2	A procedure shall exist to define compliance criteria for lot quantity checking. This procedure shall also, among others, take into consideration the tare, the density and other critical attributes.	A	
310	5.5.3	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.	A	
311	5.5.4	Results of these checks shall be compliant with defined criteria for all products ready to be delivered.	A	
312	5.5.5	For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements for nominal quantity.	N/A	No prepacked products purchased
313	5.5.6	If applicable, all equipment used for final checking shall be legally approved.	A	
314	5.6	Product analysis		

Nr.	Reference	IFS requirements	Evaluation	Explanation
315	5.6.1	There shall be procedures ensuring that all specified product requirements are met, including legal requirements and specifications. Microbiological, physical and chemical analysis required for that purpose shall be performed internally and/or subcontracted.	A	In the Company there is an internal laboratory for microbiological and chemical analyses TAB.7.5.06 “PIANO DEI CONTROLLI” Rev. 25 of 19/08/19 and PRO 8.2.00 “GESTIONE DEL LABORATORIO” Rev. 5 03/09/2016. The internal lab control plan provides control on raw material as fruit juice, acidifiers, flavours, mineral water for chemical: CBT, E.Coli, Pseudomonas, Staphylococci, fecal streptococcus, Clostridia and sulfite-reducing anaerobic bacteria, yeast, moulds, temperature, ph, calcium, magnesium, nitrates, chlorures. Packaging materials as preforms, caps, bottles and cardboard are controlled for dimension, defects and technical parameters, label are checked for conformity to specific and declarations. Internal lab is segregated from production area and perform only based chemicals and mb analysis (no pathogens analysed). All instrument are calibrated and instruction and methods available and documented. The external accredited laboratories CSA Laboratorio (Accredia no 0181L), Merieux Nutriscience (Accredia 0051) and Università di Camerino (Accredia no 0863) are in charge for chemical and microbiological determinations (TBC, P. aeruginosa, Coliforms, Streptococci and S. aureus, yeast and moulds) and sensorial analysis. Microbiological test of spring water done every 3 months last Lab CSA Accredia 0181. Ring test are carried out on 04.03.2020 between internal lab and NSF on chemical analysis of water.
316	5.6.2	Analyses, which are relevant for food safety, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/methods, the results shall be verified on a regular basis by laboratories accredited on these programs/methods (ISO 17025).	A	
317	5.6.3	Procedures shall exist which ensure the reliability of the internal analysis results on the basis of official recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
318	5.6.4	A test plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risks, which covers raw materials, semi-processed and finished products as well as processing equipments and packaging materials, and where necessary environmental tests. The test results shall be documented.	A	
319	5.6.5	Results of analysis shall be evaluated promptly. Appropriate corrective measures shall be introduced for any unsatisfactory results. The analytical results shall be reviewed regularly in order to identify trends. Trends indicating potential unsatisfactory results shall be taken into consideration.	A	
320	5.6.6	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.	A	
321	5.6.7	For verification of finished product quality, internal organoleptic tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristic. The results of these tests shall be documented.	A	
322	5.6.8	Based on hazard analysis, assessment of associated risks and on any internal or external information on product risks which may have an impact on food safety and/or quality (incl. adulteration and fraud), the company shall update its control plan and/or take any appropriate measure to control impact on finished products.	A	
323	5.7	Product quarantine (blocking/hold) and product release		

Nr.	Reference	IFS requirements	Evaluation	Explanation
324	5.7.1	A procedure shall be in place, based on hazard analysis and assessment of associated risks, for the quarantine (blocking/hold) and release of all raw materials, semi-processed and finished products and packaging materials. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.	A	
325	5.8	Management of complaints from authorities and customers		
326	5.8.1	A system shall be in place for the management of product complaints.	A	The procedure for the management of the complaint handling and responsibilities was defined: PRO 8.5.01 “Gestione NC, AC e Preventive”, issue 7 dated 04/02/2019. Positive trend over last years. From February 2019 to February 2020, 2 complaints were raised from consumers: - 22.04.2019 for sparkling mineral water with a non conforming taste. CA: counter sample with conforming results and mail sent to client; - 12.02.2020 a non sparkling mineral water. CA: counter sample with conforming results and mail sent to client Aldi. In 2020 no complaints raised. No complaints from consumers nor authorities; no complaints related to foreign material found in finished products.
327	5.8.2	All complaints shall be assessed by competent staff. Where it is justified appropriate actions shall be taken immediately, if necessary.	A	
328	5.8.3	Complaints shall be analysed with a view to implementing preventive actions which avoid the recurrence of the non-conformity.	A	
329	5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.	A	
330	5.9	Management of incidents, product withdrawal, product recall		

Nr.	Reference	IFS requirements	Evaluation	Explanation
331	5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations that impact food safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.	A	
332	5.9.2 KO	KO N° 9: There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities.	A	How many recalls have been performed since the last audit : 0 How many withdrawals have been performed since the last audit : 0 Procedure defines the key personnel who manage the incident management team: PRO 9.0 “Gestione sicurezza aziendale ed emergenza” issue 4 dated 22.08.2019. The responsibilities were determined. The company has documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. The procedure indicate, to call the certification body in 3 working days in case of real recall. Crisis team defined including QAM and Company vice president. The process was tested on 25.02.2020 on Ginger BIO 330cl batch 214/19, production dated 02.08.2020 BB 02.08.202, with client Ecor Natura Si. Mock cause: physical foreign body. Mail to client and (MOD 151): mass balance (produced and sold 51192 bottles), raw material provenance and batch, traceability of batch recall mail and crisis team summoned. Seen DDT for transport to different client (2969 dated 05.08.2019, 3001 dated 06.08.2019, 3255 dated 21.08.2019, 4386 dated 20.11.2019, 4442 dated 28.11.2019) Time: 2h. No recalls nor withdrawals in the last year
333	5.9.3	Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
334	5.9.4	The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risks but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure.	A	
335	5.10	Management of non-conformities and non-conforming products		
336	5.10.1	A procedure shall exist for the management of all non-conforming raw materials, semi-finished and finished products, processing equipment and packaging materials. This shall include, as a minimum: - isolation/quarantine procedures - hazard analysis and assessment of associated risks - identification (e.g. labelling) - decision about the further use (e.g. release, rework/post treatment, blocking, quarantine, rejection/disposal).	A	
337	5.10.2	The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.	A	
338	5.10.3	Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.	A	
339	5.10.4	Out of specification, final packaged products or packaging materials, both related to private labels, shall not be placed in the market under the label concerned. Exceptions shall be agreed in writing with the contract partners.	N/A	Out of specification products are destroyed

Nr.	Reference	IFS requirements	Evaluation	Explanation
340	5.11	Corrective actions		
341	5.11.1	A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by preventive actions and/or corrective actions.	A	
342	5.11.2 KO	KO N° 10: Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective action shall be clearly defined. The documentation shall be securely stored, and easily accessible.	A	
343	5.11.3	The performance of the implemented corrective actions shall be documented and the effectiveness shall be checked.	A	
344	6	Food defense plan and external inspections		
345	6.1	Defense assessment		
346	6.1.1	Responsibilities for food defense shall be clearly defined. Those responsible shall be key staff or shall have access to the top management team. Sufficient knowledge in this area shall be demonstrated.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
347	6.1.2	A food defense hazard analysis and assessment of associated risks shall have been performed and documented. Based on this assessment, and based on the legal requirements, areas critical to security shall be identified. Food defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect food integrity. An appropriate alert system shall be defined and periodically tested for effectiveness.	A	
348	6.1.3	If legislation makes registration or onsite inspections necessary, evidence shall be provided.	A	Sanitary authorization: 304/2007 FDA number FDA number 10567555272.
349	6.2	Site Security		
350	6.2.1	Based on a hazard analysis and assessment of associated risks, identified areas critical to security shall be adequately protected to prevent unauthorized access. Access points shall be controlled.	A	
351	6.2.2	Procedures shall be in place to prevent tampering and/or allow identification of signs of tampering.	A	
352	6.3	Personnel & Visitor Security		
353	6.3.1	Visitor policy shall contain aspects of food defense plan. Delivery and loading staff in contact with the product shall be identified and shall respect the access rules of the company. Visitors and external service providers shall be identified in areas with product storage and shall be registered at the time of access. They should be informed about the site policies and their access controlled accordingly.	A	

Nr.	Reference	IFS requirements	Evaluation	Explanation
354	6.3.2	All employees shall be trained in food defense with respect to the product requirements and the training needs of the employees or when significant program changes occur. The training sessions shall be documented. Employee hiring and employment termination practices shall consider security aspects as permitted by law.	A	
355	6.4	External Inspections		
356	6.4.1	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.	A	External inspection are conducted periodically with internal rules signed by visitors. the rules are applied for FDA too. Excetpion are managed with agreement of General Manager. Sanitary authorization: 304/2007 FDA number 10567555272

BRCGS Risk Assessment Report

Standard	**BRC ISSUE 8**	**Product Category**	*12*
Scope	*Exploitation and bottling of mineral water in glass. Production of soft drinks and flavoured water in glass bottles.*		
Exclusions from scope	*Trade Goods*		
Risk assessment result	***Certificate Extended***	**Risk assessment date(s)**	03/04/2020

Company Details			
BRCGS site code	9439107		
Company name	La Galvanina S.p.A.		
Site name	La Galvanina S.p.A.		
Address	Via della Torretta, 2 47923 RIMINI (RIMINI)		
Country	Italy	**Postcode**	47923

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

Company description	The company is composed of 2 sites both IFS certified, one located in Val di Meti and one in Rimini (the present site). The covered site area of the company is 7.800 square meters. Sanitary authorization: n° 304/2007. FDA number: 10567555272 The production process consists of pipelines and storage tanks of mineral water, depalletizer for empty bottle visual control before entering the washing equipment for glass bottles, washing, sanitizing and rinse of bottles, filler, capper, control for caps presence, labeller, printing the lot number and expiry date, wrapping or cardboard packer and palletizing. For the preparation of soft drinks dissolvers are used to warm for the ingredients, mixing, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers. 2 production lines and 30 full-time employees working on 2 shifts work. 3 HACCP Plans Dispatch turnover between national / exported products within Europe / exported products extra Europe is USA/CAN 85%, Europe 5%, ITA 10%; percentage (turnover) for retail branded products about 85%. Other schemes for the Company are IFS, UNI 10854, ISO 9001:08, ISO 14001:2004, OHSAS 18000:2007, ISO 50001:2011, Organic, Kosher and AEO_F. The name and contact data of the contact people are Matteo Spinozzi, matteo.spinozzi@galvanina.com and Matteo Matassoni, matteo.matassoni@galvanina.com Tel. 0541751315 Fax 0541-752510. IFS combination Audit. BRC Logo correctly used		
Certification Body Details			
Name of Certification Body	**SGS United Kingdom Ltd**		
Auditor(s) number	**176131**	**Auditor names and roles**	Alfredo Stefani Team Leader

Key site personnel involved in risk assessment
Only list those that were in conversation/email exchange with the auditor or certification body
Matteo Spinozzi QA Manager
Matteo Matassoni QC Manager
Roberto Valeriani QC
Roberta De Stefano QC

AGREED ACTION POINTS - SUMMARY SHEET

Any concerns following the discussion with the site that could raise doubts to continuing certification shall be documented in a similar format to 'non-conformities' and the certification body shall agree a process with the site to action these, where appropriate, so that certification can be extended. This should include an appropriate timeline (as short as possible).

Agreed action points			
No.	**Details of area of concern**	**Agreed Action Plan (where applicable)**	**Confirmation that action is completed**

Comments on any areas of concern (where applicable)
Free text box for example may be used for commentary on action plan where appropriate or any information regarding late or no submission of confirmation of completion of action plan.

Summary of each area of the risk assessment
Not Applicable (N/A) should only be used where a specific topic is not relevant to the specific Standard, for example, production line cleaning is not relevant to Agents & Brokers). Include references to any documents seen.
1. Summary of risk assessment information obtained from the site (as detailed in BRCGS072)
1.1 History of certification
Company certificate against BRC standard from 2007 Trend with Grade A, last AA
1.2 History and maturity of the BRCGS systems at the site
Company certificate against BRC standard from 2007 Trend with Grade A, last AA
1.3 Other management systems/ certification in place
IFS, ISO 14001, ISO 18001, Organic, NOP, Kosher
1.4 Critical situations throughout the site's certification history relating to BRCGS standards
None
1.5 Pending compliance activities/legal proceedings
None
1.6 Significant changes since the last BRCGS onsite audit
None
2. Summary of discussion and site procedures to manage the impact of Covid-19, including any extraordinary circumstances to the site operations and the effective implementation of any emergency response plan
2.1 Site's emergency response plan to Covid-19
The Company has developed a new procedure, the PRO 9.1 Covid-19 emergency management issue 1 dated 2020-03-25. The procedure describes the regulatory protocol for contrasting and containing the spread of the Sars-Covid19 virus. The crisis committee has been set together with the management of business trips, internal movements, meetings, internal events, training, contacts with external people and access regulation, organization of work for office and laboratories personnel, the organization of work for the staff at the production lines, the organization of the external staff, the management of a symptomatic person in the company, the disinfection and sanitation of the offices, the disinfection and sanitation of the production lines, the team of purchase, reference figures.
2.2 Significant changes to site operation in response to Covid-19/whether the site operating normally
The site contiues its activities on the same 2 shifts (05:00-13:00 and 14:00-20:00) but there is an hour's break between shifts to prevent employees from meeting during shift change. There is also a reserve-shift, to be used in case of any positivity to Covid-19 of one of the two shifts.

2.3 Summary of contingency plans including contingency supply of raw materials and any changes to processes or services outsourced following the COVID-19 emergency
A team was created to maintain the continuity of purchasing process with the assessment of the geographical location of the suppliers. The Company has decided to maintain a reserve stock of raw materials for 2 months to ensure business continuity. There are no outsourced processes.
2.4 Summary of any site requirements for additional or increased cleaning and housekeeping including any defined minimum criteria for cleaning
Cleaning methods are mentioned in Instruction 9.1, rev. 1 of 2020-03-12 which describes the sanitation of the environment and equipment. The frequency of cleaning throughout the day is fixed every 2 hours. There is also instruction 9.1B rev. 1 dated 2020-03-12 "Igienizzazione ambienti interni dello stabilimento produttivo ". Swabs are carried out to confirm correct cleanig. Seen swabs with conforming results on surface and production equipment dated 2020-03-30 and 2020-04-02 and 01.
3. Any changes to site operations due to staff shortages or the need to manage staff access, hygiene, sickness or movements
3.1 Impact of staff availability
The Company has developed a procedure, PRO 9.1 Gestione emergenze Covid issue 1 dated 2020-03-25 which regulates the staff availability and shifts. The site works on two shifts with an hour's break between shifts to prevent employees from meeting during shift change. There is a reserve-shift, to be used in case of any positivity to Covid-19 of one of the two shifts. The shifts are 2: from 05.00 to 13.00 and from 14.00 to 20.00. Processing from Monday to Friday. There is also instruction 9.2 Regole per Autotrasportatori, which regulates accesses and the methods of conduct of the transport companies.
3.2 Any additional screening or security processes for staff on arrival at site
Each time a person or employee enters the company, there is a body temperature measurement with a digital thermometer, with entry allowed only in the case of temperatures <37 ° C. After this, the changing rooms are accessed for a maximum of 2 operators at a time.
3.3 Policy for staff members who fall ill or may have been exposed to Covid-19
The Company has developed a procedure, PRO 9.1 Gestione emergenze Covid issue 1 dated 2020-03-25 which also regulates procedure in case of a syntomatic or positive to Covid19 employee: quarantine is described.
3.4 Any requirements for additional or increased hand washing
Hand washing occurs every time an employee leaves the production area and at every break. Hand sanitization points have been increased through sanitization dispensers.
3.5 Any procedures relating to staff movement
In PRO 9.1 Gestione emergenze Covid issue 1 dated 2020-03-25 is mentioned the regulation of access, the organization of work for the staff of the offices and laboratories, the organization of work for the staff at the production lines, the organization of external personnel.
3.6 Policy on access to the site and the impact on any service provision (e.g. pest control, external maintenance)
In PRO 9.1 Gestione emergenze Covid issue 1 dated 2020-03-25 is mentioned access regulation, site access policy and the impact on any external service suplpier. For pest control, carried out by Rentokill, operators come alone, are subjected to temperature control and must wear PPE to perform the service. Same procedure is applied for external maintainers, even if at this

moment external maintenance is avoided, as much as possible.
4. Internal audits
4.1 Review of internal audits schedules and implementation, to ensure that product safety systems continue to operate effectively under pressure (the auditor should review a documeted internal audit report as well as information on the schedule/process)
Internal audits are carried out and have been revised and planned with different dates. Seen audits with no observation raised carried out on: - 2019-06-08, 2019-09-25 and 2020-02-28 carried out by external consultant Dr. Rita Barbieri which provide complete checks for the BRC standard; - An internal audit was also carried out on 2019-11-19 and 2020-03-02, done by Lorenzo Valeriani AQ on the water botlting lines; - Another audit on 2020-03-02 made by Roberta De Stefano QC on bottling lines.
5. Review of complaints, recalls and withdrawals and the management of these
5.1 Recent customer complaint levels or trends
No product recalls nor withdrawals in the last 15 months. There are only 2 complaints in 2019-2020: - The first dated 2019-04-02 for spring water in 0.750 glass bottles with an unpleasant taste, Corrective Action: checked the counter-samples and analyses were carried out, no problems were found on the counter sample in the Company; - Another complaint dated 2020-02-12 on sparkling water in glass by customer A. who claimed that the water was not sparkling. Since the batch had not been returned by the client, it was not possible to verify the validity of this complaint.
5.2 Product recalls since the last BRCGS audit
No product recalls nor withdrawals in the last 15 months. The last mock test on withdrawal and recall was carried out by the Company on 2020-02-25 on the product Ginger Bio 330 ml, mock scenario: wrong batch. Mass balance carried out with quantity produced, 51192 pieces and Batch L214 / 19 verified . Seen quantity shipped and potentially recallable. Seen mail to client. Time taken 2 hours.
5.3 Any root cause and corrective actions as a consequence of complaints, recalls or withdrawals (where appropriate)
No product recalls nor withdrawals in the last 15 months. The 2 complaints raised from March 2019 to March 2020 were correctly managed, e.g. for compaint dated 2019-04-02 for spring water in 0.750 glass bottles with an unpleasant taste, checked the counter-samples and analyses were carried out, no problems were found on the counter sample in the Company.
6. Management Meetings
6.1 Evidence of appropriate management meetings/discussion/actions
Management review dated 2020-03-02, which involved 8 people. Last monthly meeting dated 2020-03-02. Meeting committments are held once a week, e.g. last one dated 2020-03-31 with Massimo Ambrosini (CEO), Ubaldo Bertozzi (Director of Val di Meti Site), Achille Marino (Director of Galvanina Site), Matteo Spinozzi (Director of Via Popilia Site), Matteo Matassoni (Quality Manager), Nicolò Tommasoni (CFO), Lorenzo Faggioli (Internal lawyer), Pesini Fabio (President) and Marcello Agradi (Purchasing Manager). In those meetings, emergency measues and procedure for Coronavirus were discussed and set.
7. Additional information
7.1 Any other additional information collected during the risk assessment process
The Company guarantees the continuity of the production object of the certification, seen communication to customers dated 2020-03-09 which emphasizes that the Company has put in place all activities aimed at maintaining business continuity, without delays in delivery of orders.

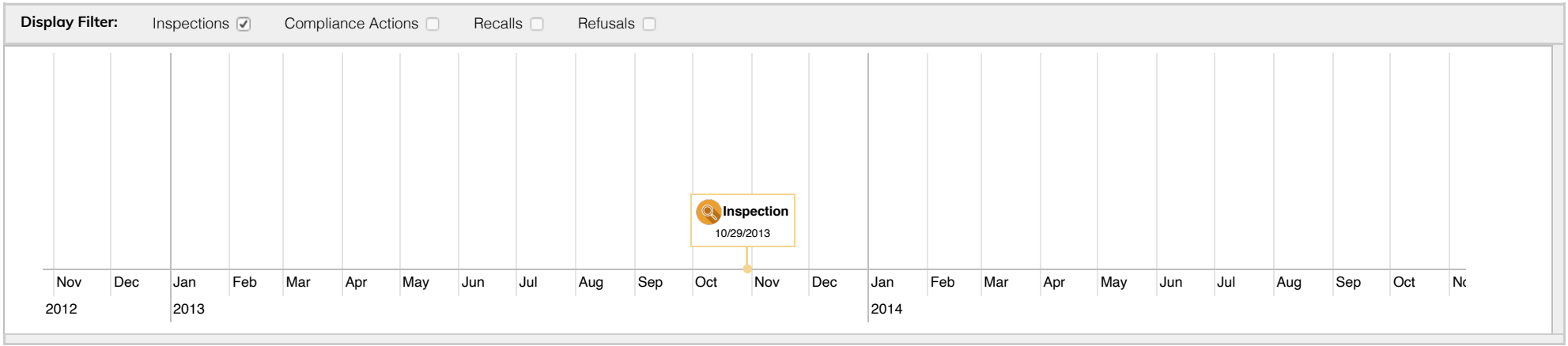

120 mm (4.724")
CF2H
SX
OVERLAP / SORMONTO
56 mm (2.204")
GALVANINA
ORGANIC
FRŪ.IT
ITALIAN SPARKLING
FRUIT BEVERAGE
WITH PULP
USDA
ORGANIC
BLOOD ORANGE
12 FL OZ (355 mL)
Product of Italy
PRODUCED BY:
LA GALVANINA S.P.A.
47923 RIMINI - ITALY
www.galvanina.com
INGREDIENTS: CARBONATED WATER, BLOOD ORANGE JUICE*, CANE SUGAR*, LEMON JUICE*, CITRUS PULP*, RED GRAPEFRUIT JUICE*, BLACK CURRANT JUICE*, ELDERBERRY JUICE*, BLACK CARROT JUICE*, CITRIC ACID, NATURAL FLAVORS, *FROM ORGANIC FARMING - JUICE FROM CONCENTRATE.
CONTENT UNDER PRESSURE. HANDLE WITH CARE. REFRIGERATE AFTER OPENING AND CONSUME WITHIN THREE DAYS. SINCE THE PRODUCT IS NATURAL SEDIMENTATION MAY OCCUR. BEST BEFORE : SEE CAP.
CONTAINS 24% JUICE and 1% PULP
Certified Organic by Ecogruppo Italia IT BIO 008
Nutrition Facts Servings: 1; Serv. size: 1 bottle,
Amount per serving: Calories 160, Total Fat 0g (0% DV), Sat. Fat 0g (0% DV), Trans Fat 0g, Cholest. 0mg (0% DV), Sodium 35mg (2% DV), Total Carb. 41g (15% DV), Fiber 0g (0% DV), Total Sugars 40g (Incl. 34g Added Sugars 68% DV), Protein 0g, Fat 0g (0% DV), Potas. (0% DV), Iron (0% DV), Calcium (0% DV), Vit. D (0% DV)
CA CRV; CT, HI, IA, MA, ME, NY, VT, 15¢; OR, MI ref 10¢
8 29943 75330 7

FEI Number
3003097690

Firm Name
La Galvanina S.p.A.

Firm Address
Via della Torretta N. 2
Rimini,
Italy

FDA Actions Timeline



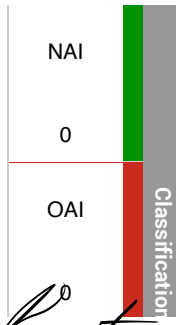
3003097690 – La Galvanina S.p.A.

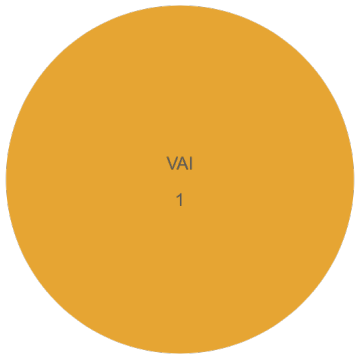
Inspections

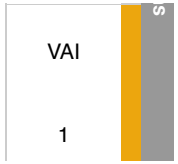
Inspections	Classifications
1	1

Inspection Classifications by Fiscal Year
Fiscal Years: 2014 - 2014

Inspection Classifications by Type
Fiscal Years: 2014 - 2014







Inspections Details

Inspection ID	Inspection End Date	Project Area	Product Type	Classification	
853158	10/29/2013	Foodborne Biological Hazards	Food/Cosmetics	VAI	

3003097690 – La Galvanina S.p.A.

Inspections Citations Details

Claudio Innocenti

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Compliance Actions

Warning Letters	Injunctions	Seizures
0	0	0

Actions by Percentage

Fiscal Years: 2009 - 2020

No data found for the selected firm

Compliance Actions Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Recalls

Recalled Products by Classification
Fiscal Years: 2012 - 2020

No data found for the selected firm

Recall Events by Status
Fiscal Years: 2012 - 2020

No data found for the selected firm

Recalls Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Import Refusals

Refusals by Product Category

Fiscal Years: 2002 - 2020

No data found for the selected firm

Import Refusals Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Import Alerts

- The search results below should be reviewed to determine whether the firm's products are allowed into the country.
- Only current/active Import Alerts are displayed. For more information see Import Alerts.

No Import Alerts data found for the selected firm.

Claudio Innocenti

3003097690 – La Galvanina S.p.A.

Warning Letters

- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see Warning Letters.

No Warning Letters data found for the selected firm.

Caveats:

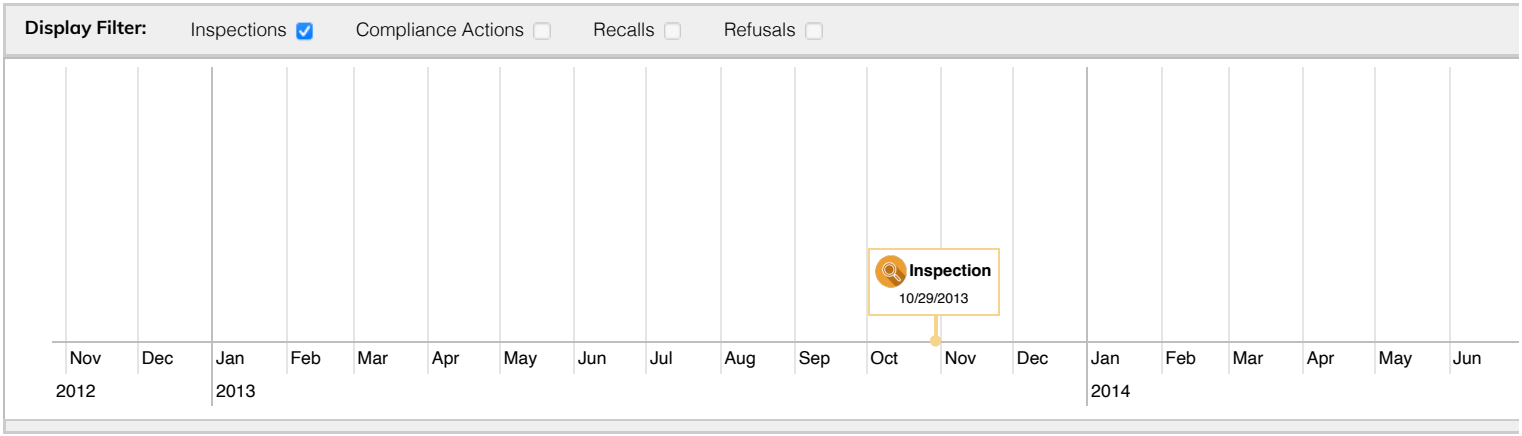
- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated monthly and only include final actions. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.
- Compliance data provide information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injunctions. The compliance actions disclosed include only finalized and completed actions and are primarily used in the domestic arena.
- More than one establishment may be associated with one compliance action. The counts provided in this section reflect the number of establishments linked to the compliance action.
- For more information regarding the Center for Tobacco Products (CTP) issued warning letters click here.

FEI Number
3003097690

Firm Name
La Galvanina S.p.A.

Firm Address
Via della Torretta N.
Rimini, Rimini 4792
Italy

FDA Actions Timeline



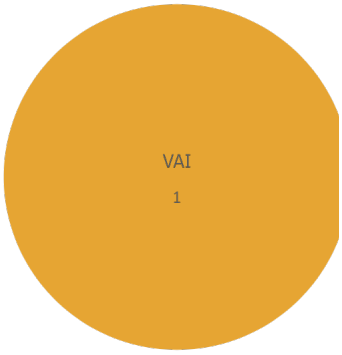
3003097690 – La Galvanina S.p.A.

Inspections

Inspections	Classifications
1	1

Inspection Classifications by Fiscal Year
Fiscal Years: 2014 - 2014

Inspection Classifications by
Fiscal Years: 2014 - 2014



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Inspection ID	Inspection End Date	Project Area	Product Type	Classification
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3003097690 – La Galvanina S.p.A.

Inspections Citations Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Compliance Actions

Warning Letters	Injunctions	Seizures
0	0	0

Actions by Percentage

Fiscal Years: 2009 - 2022

No data found for the selected firm

Compliance Actions Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Recalls

Recalled Products by Classification

Fiscal Years: 2012 - 2022

No data found for the selected firm

F

No d

Recalls Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Import Refusals

Refusals by Product Category

Fiscal Years: 2002 - 2022

No data found for the selected firm

Import Refusals Details

No data found for the selected firm

3003097690 – La Galvanina S.p.A.

Import Alerts

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No Import Alerts data found for the selected firm.

3003097690 – La Galvanina S.p.A.

Warning Letters

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Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3003097690	La Galvanina S.p.A.	Via della Torretta N. 2, Rimini, Rimini, 47923, IT	Via della Torretta N. 2, Rimini, Rimini, 47923, IT